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(54) **CATHETER WITH ADJUSTABLE ARCUATE DISTAL SECTION**

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(58) **Field of Classification Search**
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(57) **ABSTRACT**

A catheter includes an elongated body, a distal assembly with a shape-memory member defining a generally circular form, and a control handle adapted to actuate a deflection puller wire for deflecting a portion of the elongated body, and a contraction wire for contracting the generally circular form. The generally circular form which carries at least one ring electrode has an off-edge configuration relative to the elongated body such that a longitudinal axis of the elongated body does not intersect the circumference of the circular form and the generally circular form spirals about the longitudinal axis of the elongated body. Moreover, the circular form can have an on-axis configuration such that the longitudinal axis of the elongated body is axially aligned with a central longitudinal axis of the circular form, or an off-axis configuration such that these axes are axially offset from each other. In a more detailed embodiment, the catheter has a distal assembly with a helical form or a crescent form carrying a plurality of irrigated ablation ring electrodes and
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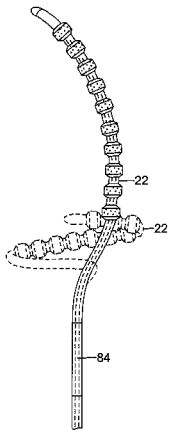

a plurality of smaller ring electrodes adapted for impedance recording or PV potential recording. A support member with shape memory extends through the distal assembly to provide the helical or crescent form. The support member has a varying stiffness along its length, for example, a decreasing stiffness toward a distal end of the support member. The support member can also be hollow so that it can receive a mandrel whose stiffness is greater than that of the support member.

18 Claims, 15 Drawing Sheets

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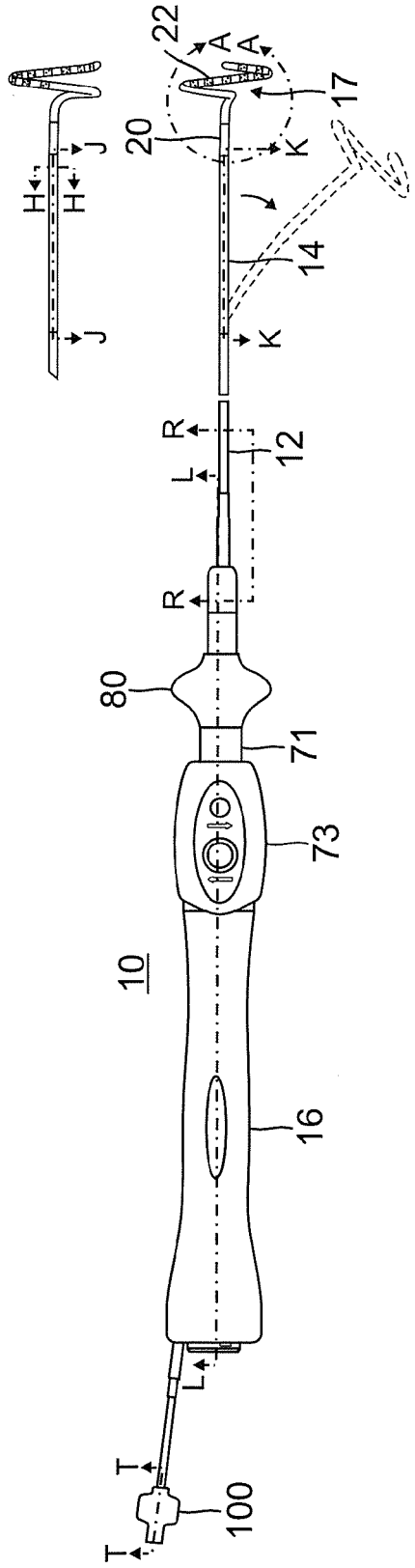
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L
12
R
80
71
73
10
16
L
T
T
100
T

FIG. 1

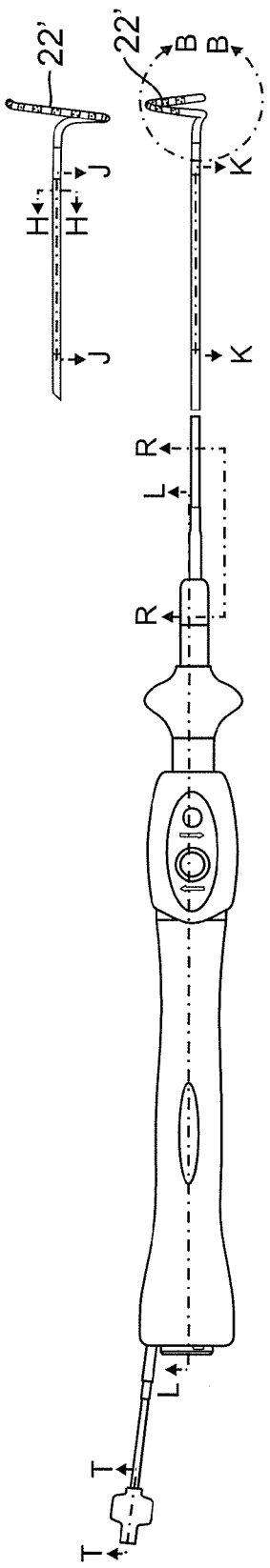

22'
22'
B
B
K
H
H
J
J
K
R
L
R
L
T
T
T

FIG. 18

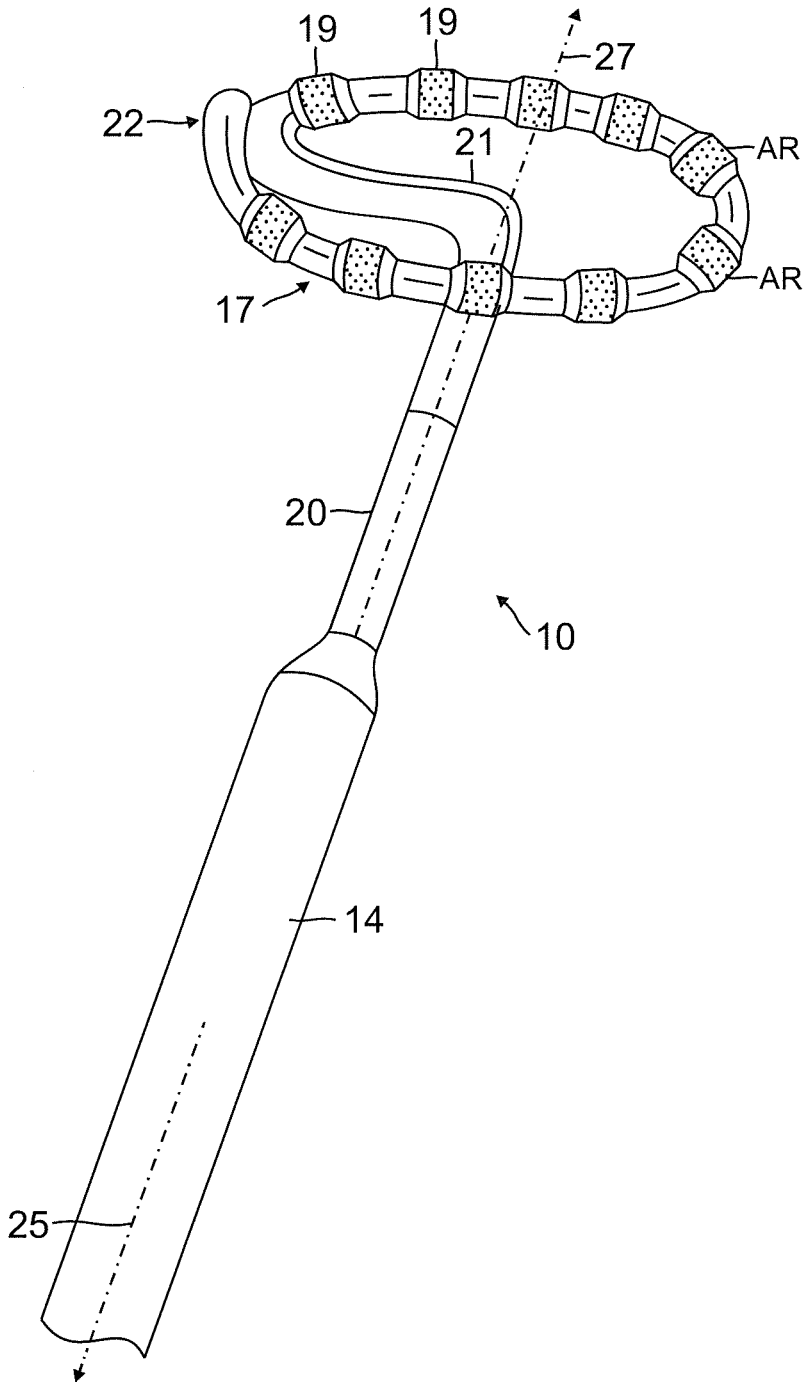


FIG. 2

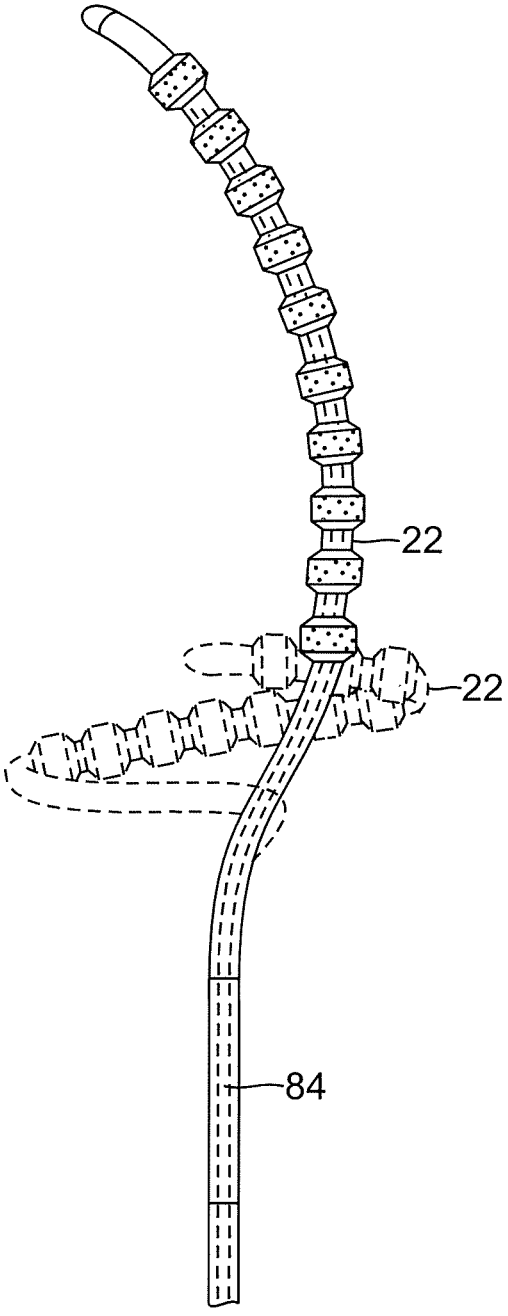


FIG. 3

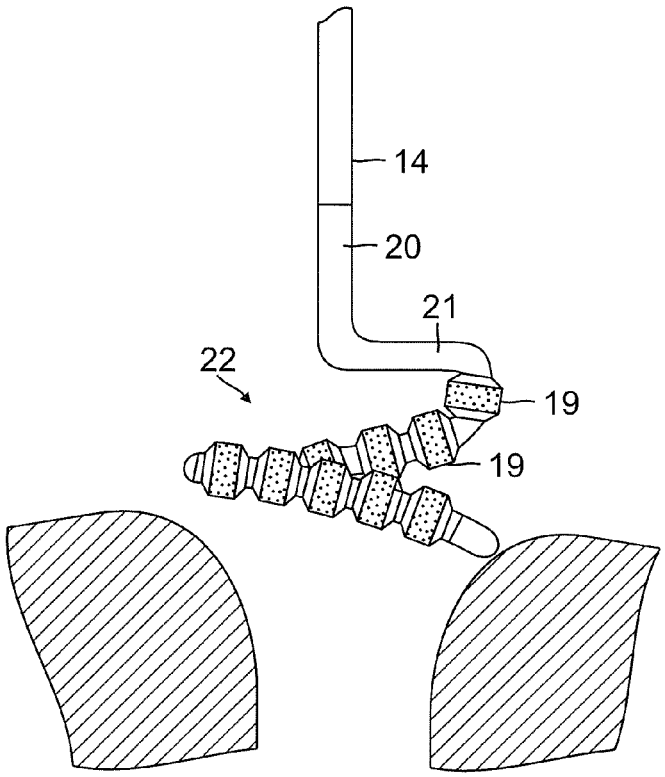


FIG. 4A

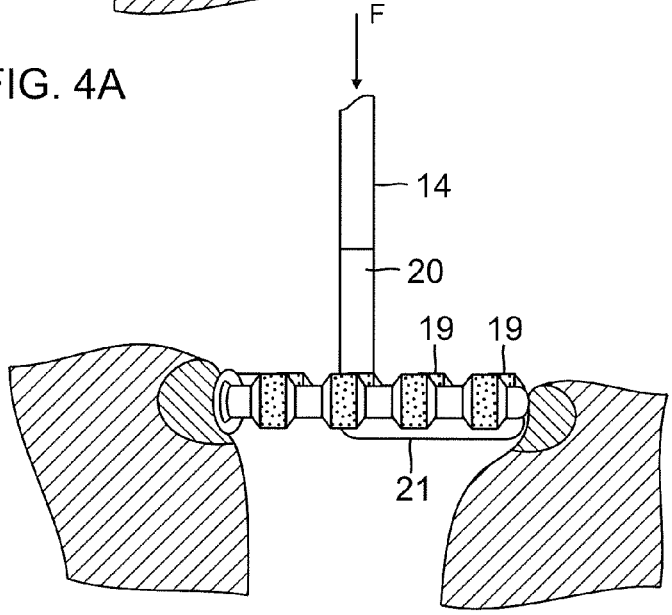


FIG. 4B

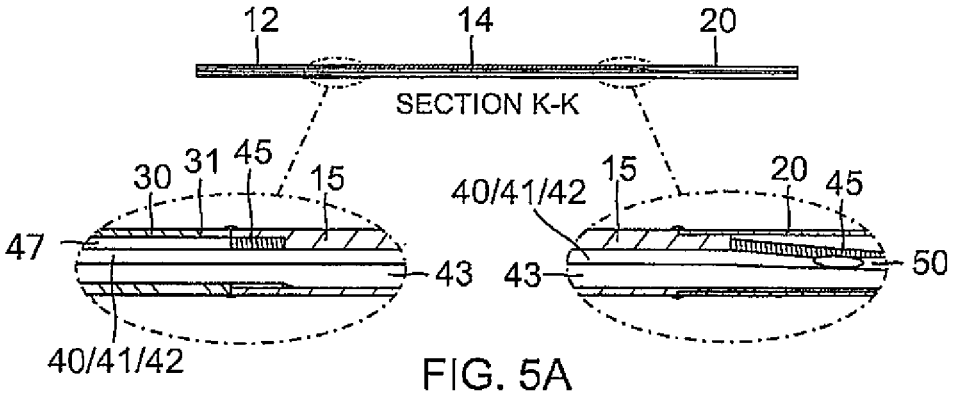


FIG. 5A

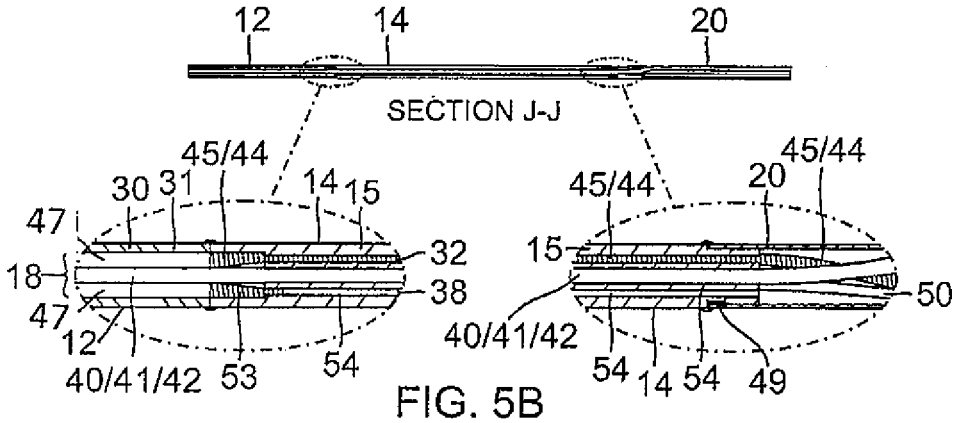


FIG. 5B

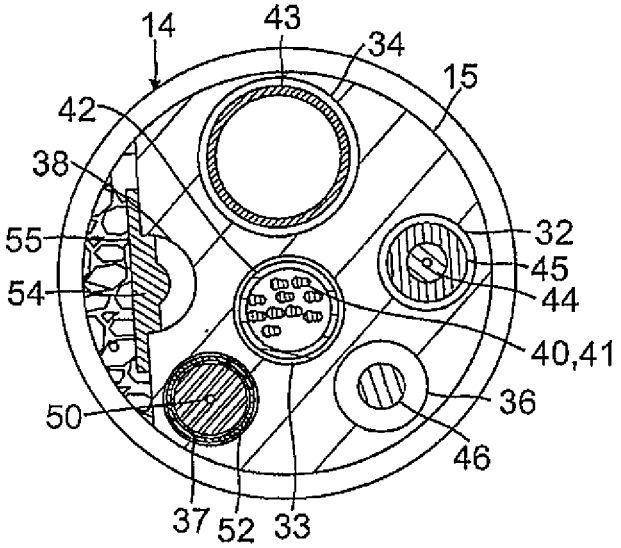


FIG. 6

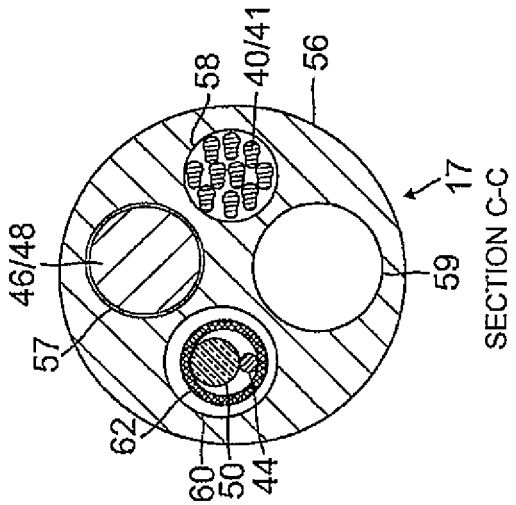


FIG. 11

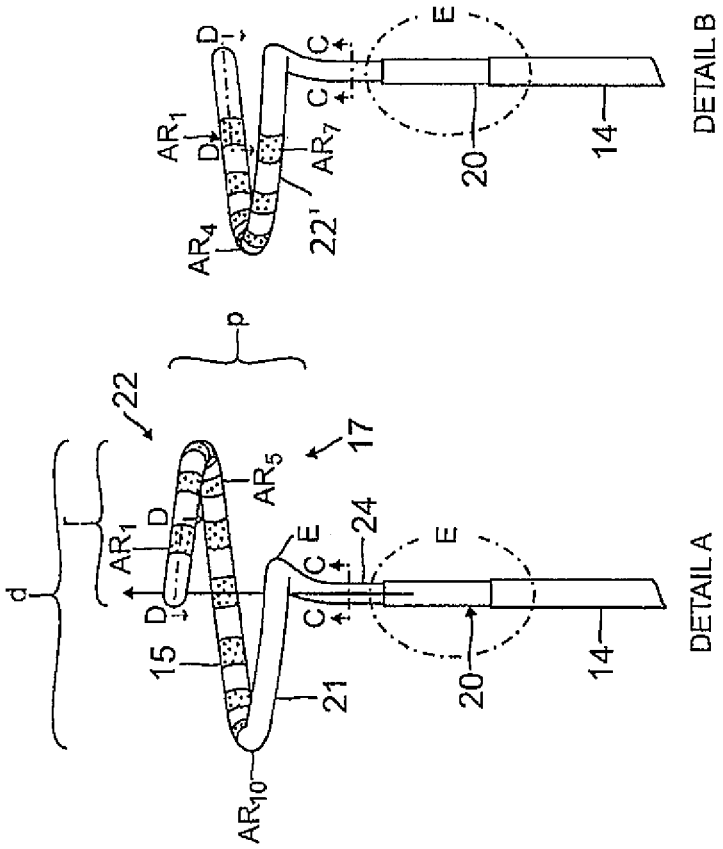
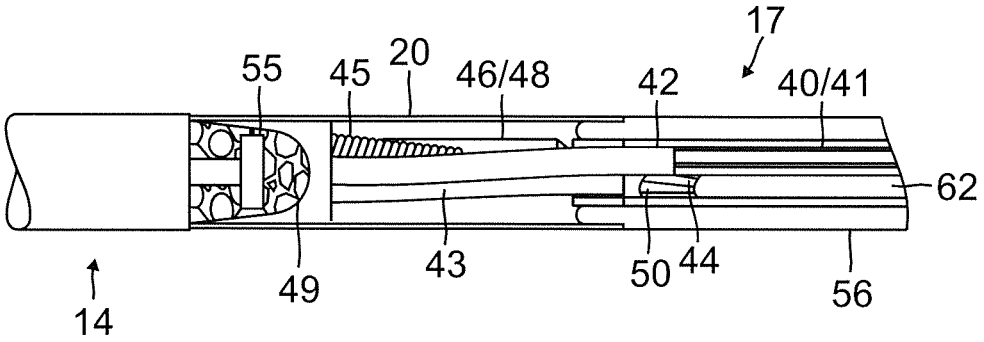


FIG. 7

FIG. 19


17
55
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20
46/48
42
40/41
62
14
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43
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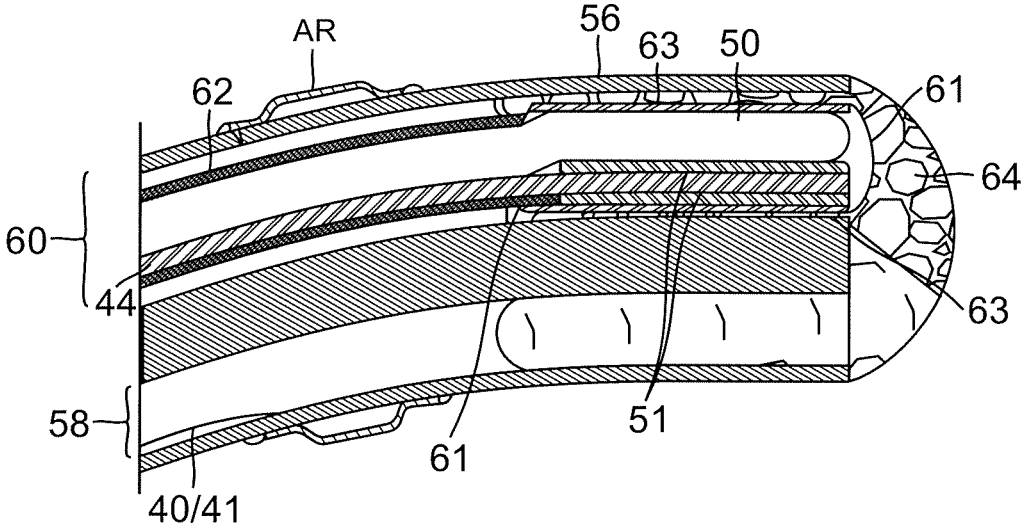
44
56

FIG. 8


AR
56
63
50
62
61
64
60
44
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58
51
61
40/41

FIG. 12

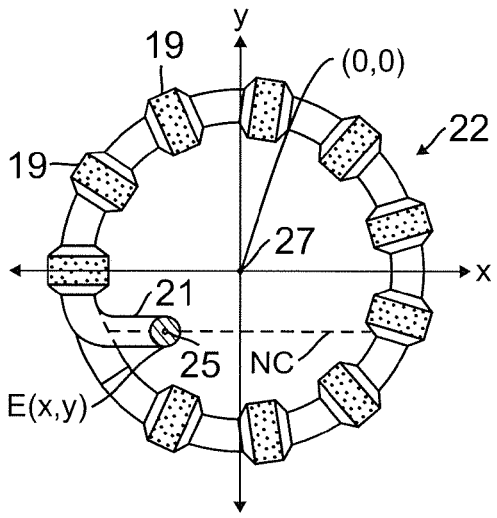


FIG. 9C

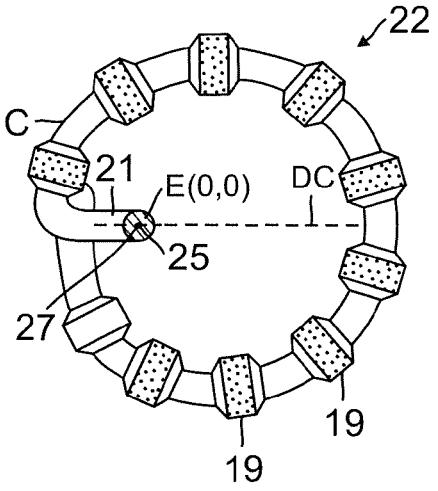


FIG. 9A

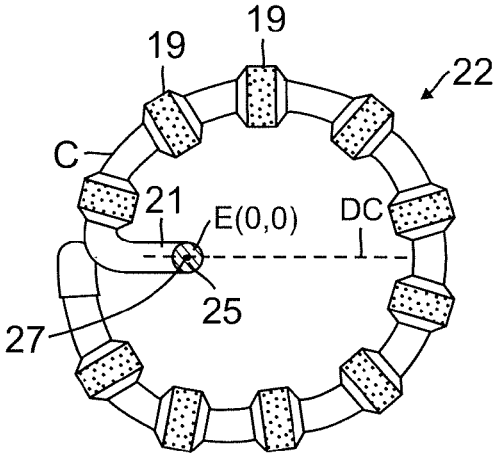


FIG. 9B

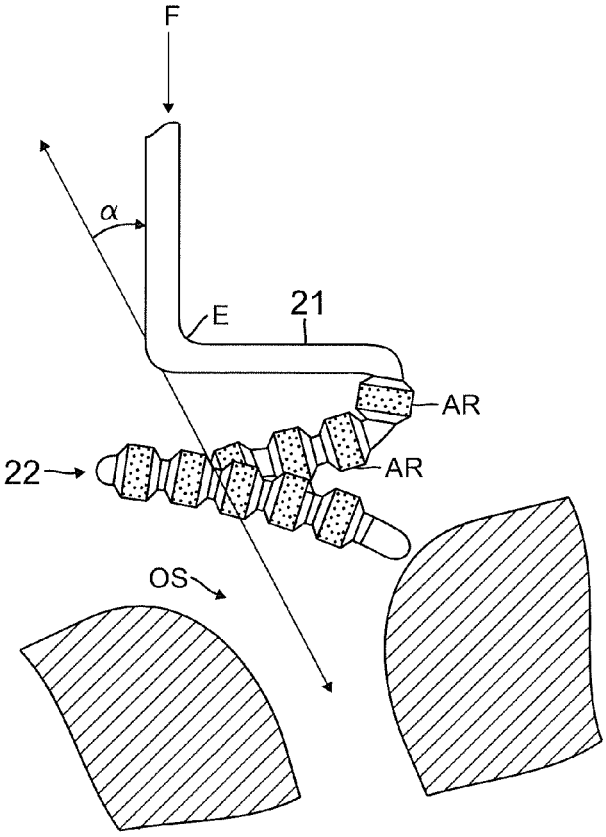


FIG. 10A

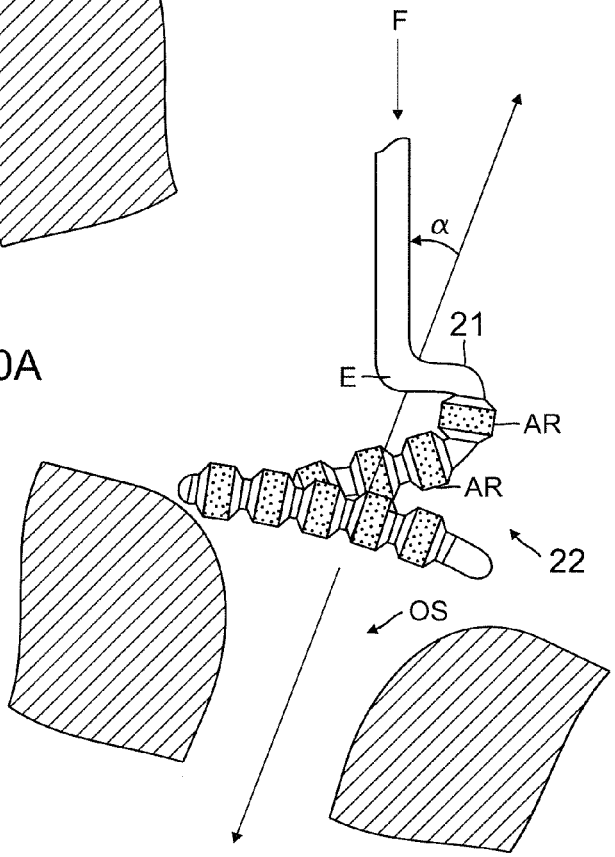


FIG. 10B

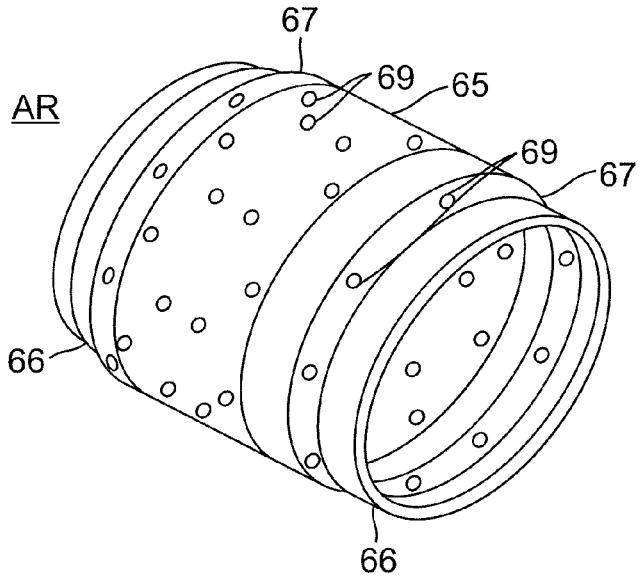
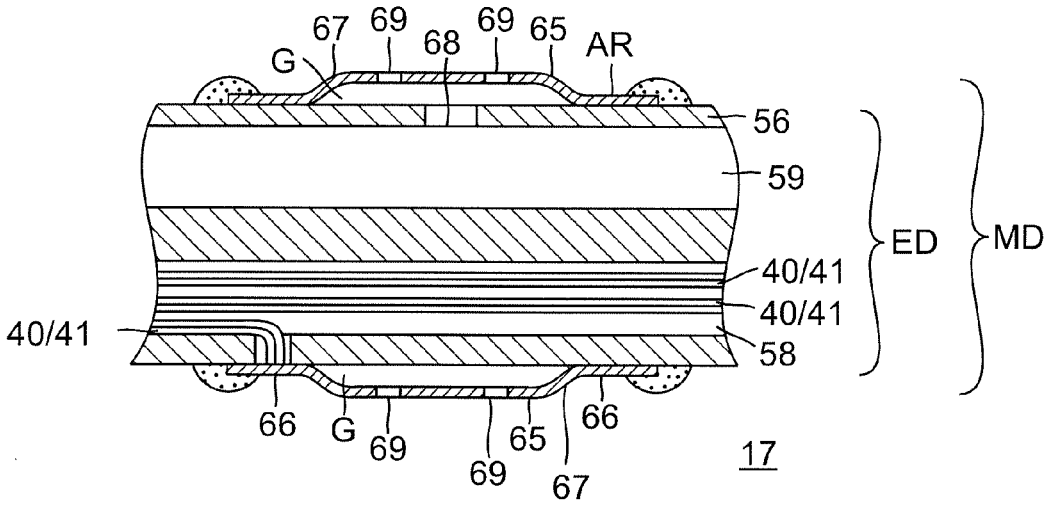

67
69
65
AR
69
67
66
66

FIG. 13


67
69
68
69
65
AR
G
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MD
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40/41
58
66
G
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69
65
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67
17

FIG. 14

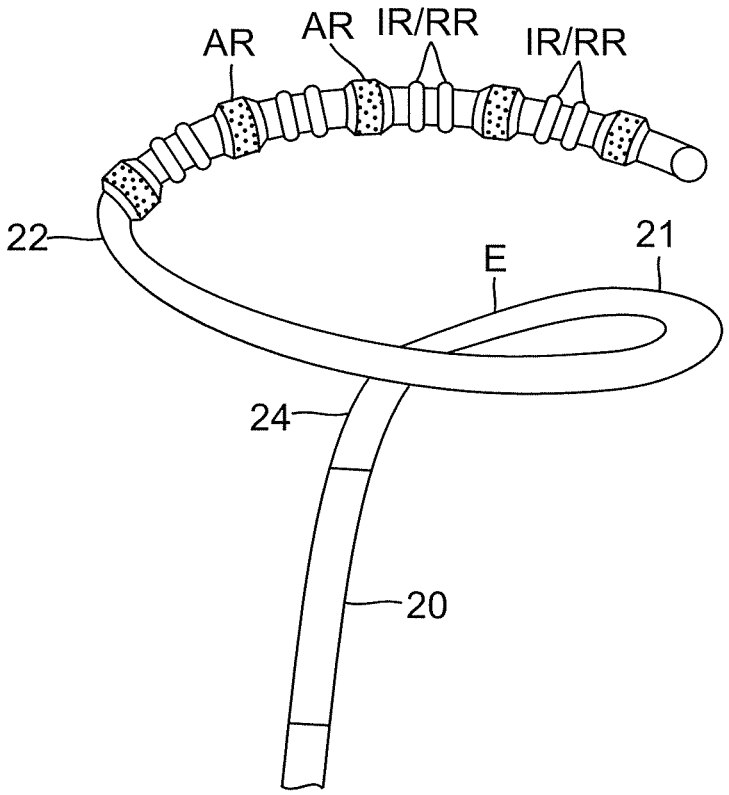

FIG. 15

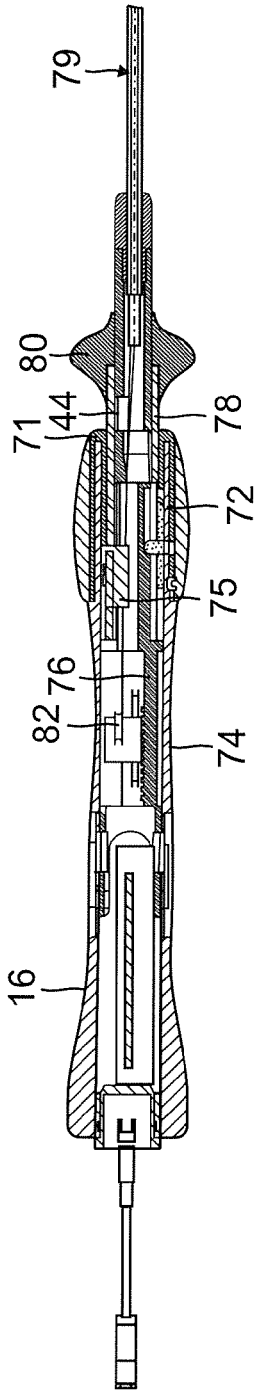

FIG. 16

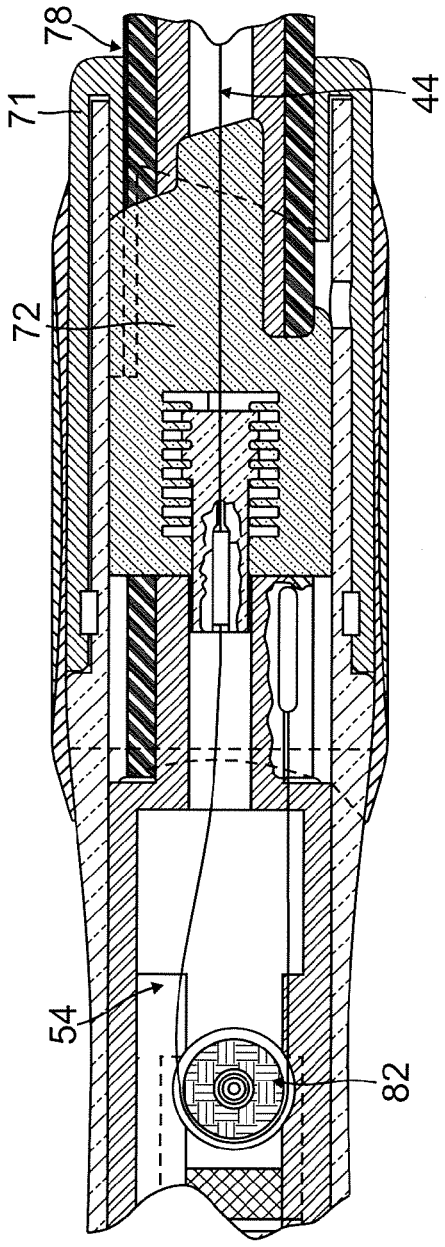

FIG. 17

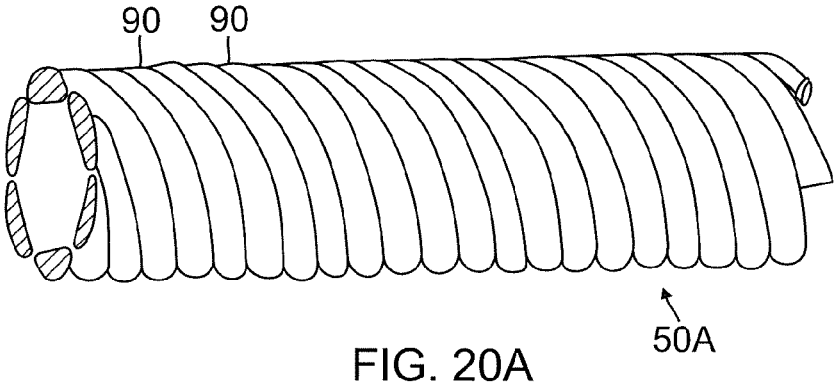

FIG. 20A

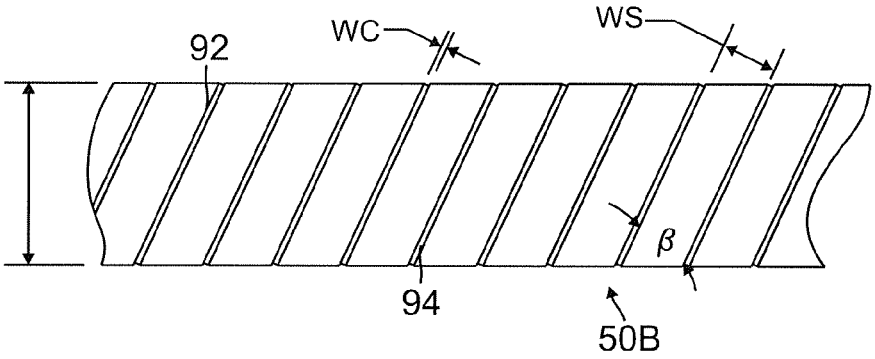

FIG. 20B

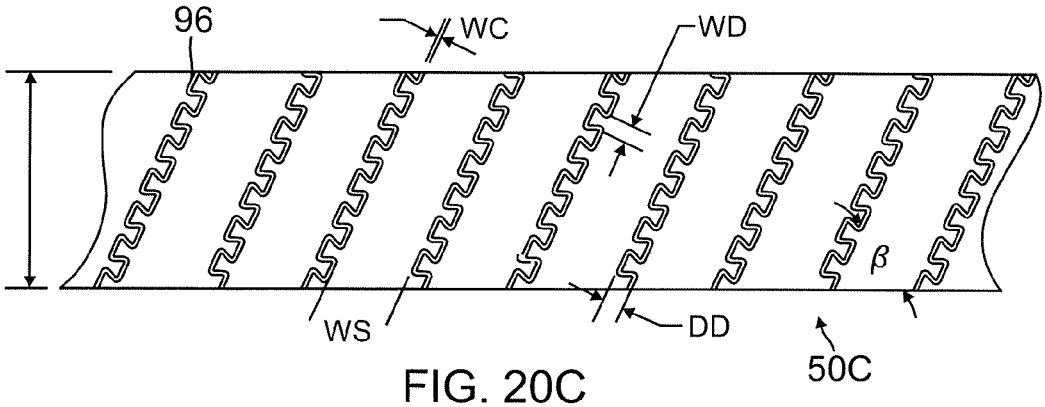

FIG. 20C

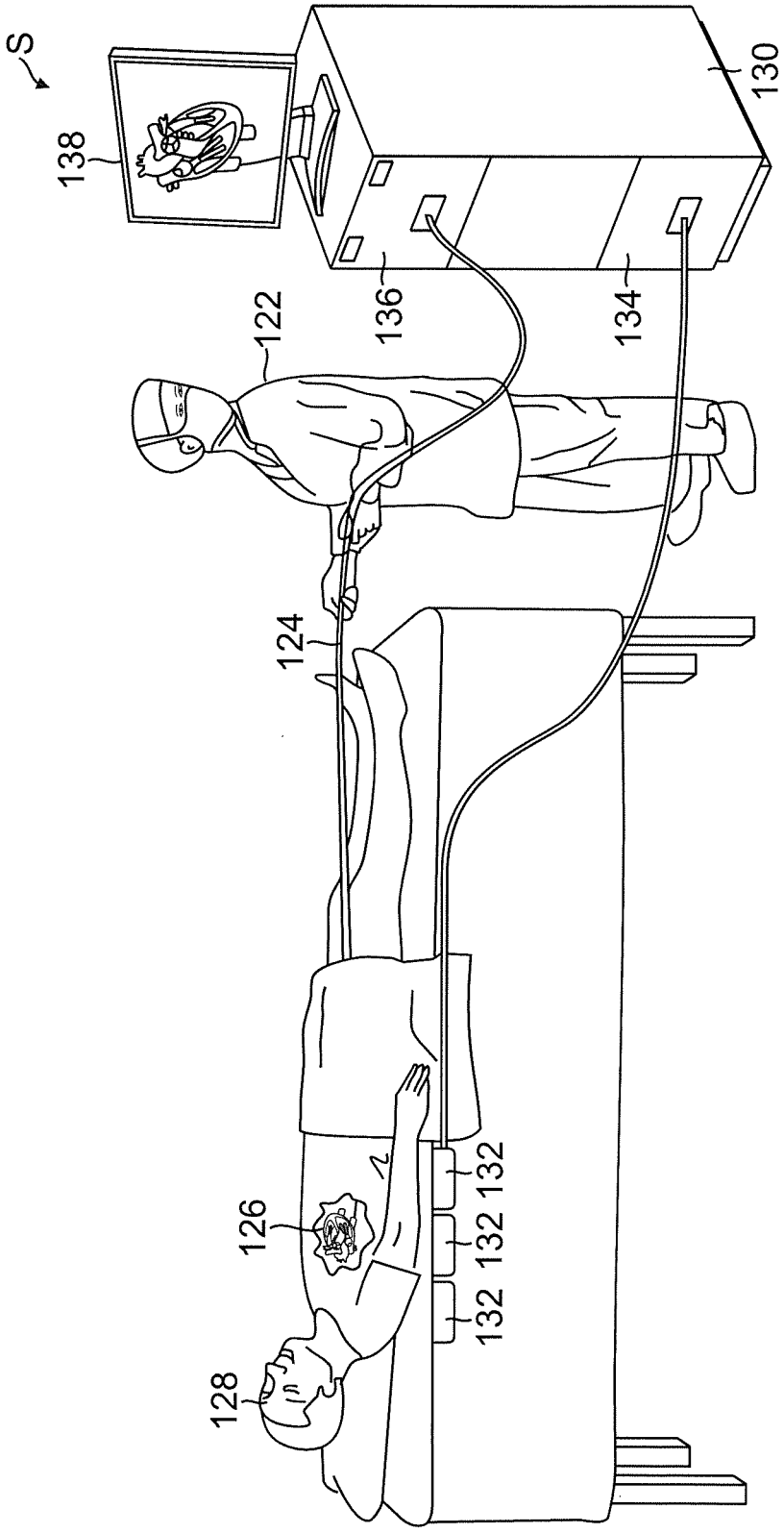

FIG. 21

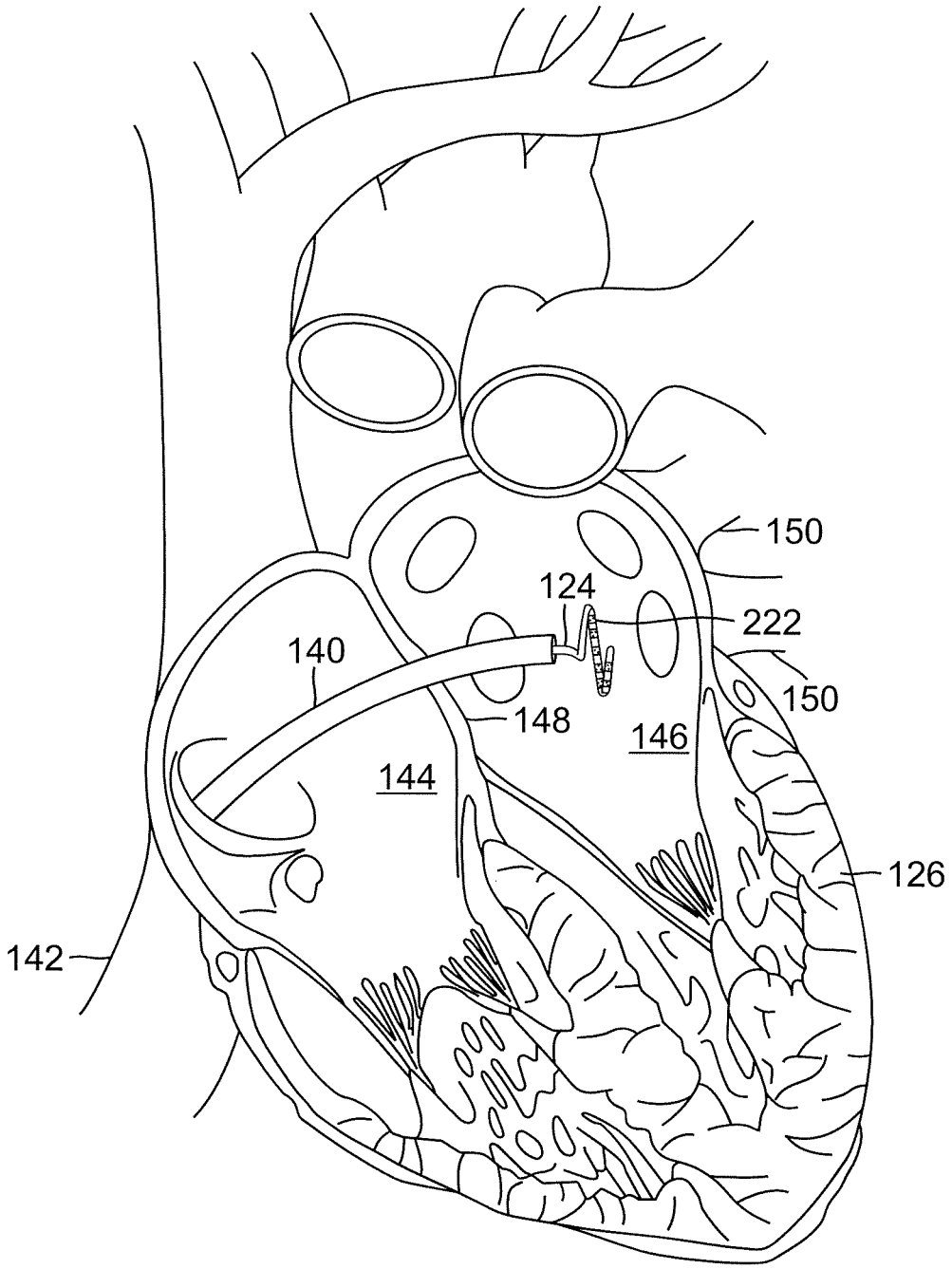

FIG. 22

CATHETER WITH ADJUSTABLE ARCUATE DISTAL SECTION

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation of and claims priority to and the benefit of U.S. patent application Ser. No. 13/174,742 filed Jun. 30, 2011, issued as U.S. Pat. No. 9,220,433, the entire content of which is incorporated herein by reference.

FIELD OF INVENTION

This invention relates generally to methods and devices for invasive medical treatment, and specifically to catheters, in particular, catheters having distal sections adapted for mapping and ablating selected anatomy.

BACKGROUND

Ablation of myocardial tissue is well known as a treatment for cardiac arrhythmias. In radio-frequency (RF) ablation, for example a catheter is inserted into the heart and brought into contact with tissue at a target location. RF energy is then applied through an electrode on the catheter in order to create a lesion for the purpose of breaking arrhythmogenic current paths in the tissue.

Recently, circumferential ablation of the ostia of the pulmonary vein has gained acceptance as a treatment for atrial arrhythmias, and particularly for atrial fibrillation. For example, U.S. Pat. No. 6,064,902, whose disclosure is incorporated herein by reference, describes a catheter for ablating tissue on the inner wall of a blood vessel, such as a pulmonary vein. The tip portion of the catheter is deflectable from a first, generally straight, configuration, in which the proximal and distal sections are substantially co-linear, to a second, J-shaped, configuration in which the proximal and distal sections are generally parallel with a separation therebetween substantially corresponding to the inside diameter of the blood vessel. The distal end portion of the catheter is rotated about the longitudinal axis of the catheter to cause a circumferential displacement of proximal and distal ablation electrodes on the catheter along the inner wall of the pulmonary vein. In this way, the electrode catheter may be used to ablate a number of circumferentially-spaced sites on the inner wall of the pulmonary vein by ablating one or two sites at each circumferential position.

U.S. Patent Application Publication 2005/0033135, whose disclosure is incorporated herein by reference, describes a lasso for pulmonary vein mapping and ablation. A catheter for circumferentially mapping a pulmonary vein (PV) includes a curved section shaped to generally conform to the shape of the interior surface of the PV. The curved section is connected to catheter by a generally straight axial base section that is in an "on edge" configuration where the base axial section connects to the curved section on the circumference of the curved section. The curved section comprises one or more sensing electrodes, and its proximal end is joined at a fixed or generally known angle to a base section of the catheter. Position sensors are fixed to the curved section of the catheter and to the distal end of the base section. The catheter is inserted into the heart, and the curved section is positioned in contact with the wall of the PV, while the base section remains within the left atrium, typically positioned such that the joint with the curved section is at the ostium of the vein. The information generated by the three position sensors is used to calculate the locations and orientations of the sensing electrodes, which enables mapping of the surface of the PV. The sensing electrodes may additionally perform ablation of selected sites, or the catheter may further comprise ablation elements.

U.S. Pat. No. 7,008,401, whose disclosure is incorporated herein by reference, describes compound steering assemblies, usable in both diagnostic and therapeutic applications, for steering the distal section of a catheter in multiple planes or complex curves. These assemblies are said to enable a physician to swiftly and accurately position and maintain ablation and/or mapping electrodes in intimate contact with an interior body surface. U.S. Pat. No. 5,820,591, whose disclosure is incorporated herein by reference, similarly describes compound steering assemblies of this sort.

U.S. Patent Publication No. 2011/0160719, filed on Dec. 30, 2009, whose disclosure is incorporated herein by reference, describes a medical device, including an insertion shaft, having a longitudinal axis and having a distal end adapted for insertion into a body of a patient. A resilient end section is fixed to the distal end of the insertion shaft and is formed so as to define, when unconstrained, an arc oriented obliquely relative to the axis and having a center of curvature on the axis. One or more electrodes are disposed at respective locations along the end section.

However, because human anatomy varies between individuals, the shape and size of an ostium vary, and the end section whether having an arcuate shape or a generally circular shape may not always fit the particular target ostium. Moreover, because the right atrium is a confined volume, the approach into a PV ostium is often times indirect in that the base section does not always assume a perpendicular angle to the target site. Because of these factors, contact between the electrodes and the ostium is often less than complete.

Accordingly, a desire exists for a lasso-type catheter that can provide an end section whose curved (or circular, used interchangeably herein) portion can be varied to fit differently-sized ostia. Moreover, by providing an end section with a curved portion that is supported "off-edge" by the catheter, the curved portion is better adapted to distribute the load for more complete tissue contact when an axial force is applied to the catheter during mapping or ablation. Furthermore, the curved portion can be supported either "axis" or off-axis" by the catheter, where an on-axis configuration may be better suited for a straight-on approach toward an ostium and an off-axis configuration may be better suited for an angled approach toward an ostium. There is also a further desire for such catheter to provide accurate tissue contact verification and/or accurate visualization of PV potentials during ablation with the use impedance and/or PV potential recording electrodes.

SUMMARY OF THE INVENTION

The present invention is directed to a catheter whose distal assembly has a curved (or circular) configuration that can be varied by means of a contraction wire actuated by a control handle and/or the use of a mandrel that is inserted into the distal assembly. For improved surface contact between the electrodes and the target tissue, e.g., a PV ostium, the distal assembly includes a radially transverse section that supports the electrode-bearing curved portion of the distal assembly in an "off-edge" manner which allows a better, more controlled distribution of load on the electrode-bearing curved portion when an axial force is applied to the catheter during mapping and/or ablation. The electrode-

bearing curved portion of the distal assembly may be centered on the catheter where it is supported in an "on axis" manner such that a center of the curved portion is on or axially aligned with a longitudinal axis of the catheter. Alternatively, the electrode-bearing curved portion is supported in an "off-axis" manner where the center of the curved portion is axially offset from the longitudinal axis of the catheter.

The configuration of the electrode-bearing portion of the distal assembly is generally curved or circular, including a helical form or a crescent shape, for mapping and/or ablating tubular regions, such as a PV ostium. The helical form is tapered, either expanding in radius or decreasing in radius along its spiral. A support member with shape memory provides the desired configuration in the distal assembly and its flexibility can vary along its length. For example, the helical form may be stiffer in the proximal portion for withstanding load and more flexible in the distal portion for easier contraction. Such variable stiffness can be accomplished by varying the thickness of the support member, such as having a thicker proximal portion and a thinner distal portion.

To minimize the risk of charring, ablation ring electrodes carried on the distal assembly are irrigated. The ablation ring electrode has an enlarged mid-section so as to provide an annular gap or reservoir around the tubing carrying the ring electrode so that flow distribution to outside the electrode through apertures in the side wall of the ablation ring electrode is improved. Apertures are also provided in opposing end portions of the ring electrodes so that irrigation flows in the radial direction, as well as in the axial direction.

Whereas a contraction wire can be actuated via the control handle to contract the distal assembly, a mandrel can be inserted through the distal assembly, or in particular, through the support member, to vary or alter the form of the electrode-bearing curved portion of the distal assembly. To facilitate this adjustment or variation, the support member can be hollow so as to receive the mandrel therethrough. To increase flexibility of the support member so that it can yield to the predetermined form of the mandrel while maintaining sufficient rigidness so that it can return its own predetermined form in the absence or withdrawal of the mandrel, the support member may be formed from a bundle of wires coiled in a spiral, or it may be a tubular member with a spiral cut along its length. The spiral cut may be smooth, or it may have an interlocking pattern such that the support member provides the desired flexibility without elongation in the axial direction.

The electrode-bearing portion of the distal assembly may include smaller and/or more closely spaced-together ring electrodes for impedance and/or PV potential recording. Accordingly, a single catheter can perform simultaneous ablation, mapping (electrogram recording) and assessment of tissue contact.

In one embodiment, the catheter includes an elongated body, and a distal assembly with a shape-memory member defining a generally circular form. The catheter further includes a control handle adapted to actuate a deflection puller wire for deflecting a portion of the elongated body, and a contraction wire for contracting the generally circular form. The generally circular form which carries at least one ring electrode has an off-edge configuration relative to the elongated body such that a longitudinal axis of the elongated body does not intersect the circumference of the circular form and the generally circular form spirals about the longitudinal axis of the elongated body. Moreover, the circular form can have an on-axis configuration such that the longitudinal axis of the elongated body is axially aligned with a central longitudinal axis of the circular form, or an off-axis configuration such that these axes are axially offset from each other.

In a more detailed embodiment, the catheter has a distal assembly with a helical form or a crescent form carrying a plurality of irrigated ablation ring electrodes and a plurality of smaller ring electrodes adapted for impedance recording or PV potential recording. A control handle has a first control member that draws a contraction wire for contracting the helical or crescent form, and a second control member that draws a deflection wire for deflecting an intermediate section proximal of the distal assembly. A support member with shape memory extends through the distal assembly to provide the helical or crescent form. The support member has a varying stiffness along its length, for example, a decreasing stiffness toward a distal end of the support member.

In another more detailed embodiment, the support member is hollow so that it can receive a mandrel whose stiffness is greater than that of the support member so that the support member can yield to and generally assume the predetermined form of the mandrel. The support member may be of a hollow strand tube construction, or it may be a tubular construction with a spiral cut with either a smooth pattern or an interlocking pattern.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings. It is understood that selected structures and features have not been shown in certain drawings so as to provide better viewing of the remaining structures and features.

FIG. **1** is a top plan view of an embodiment of a catheter in accordance with the present invention.

FIG. **2** is a perspective view of an embodiment of a distal end portion of a catheter of the present invention, including a distal assembly.

FIG. **3** is a perspective view of an embodiment of a distal assembly.

FIG. **4**A is a side view of an embodiment of a distal assembly approaching an ostium straight on.

FIG. **4**B is a side view of the distal assembly of FIG. **4**A in contact with the ostium.

FIG. **5**A is a side cross-sectional view of the catheter of FIG. **1**, taken along line J-J.

FIG. **5**B is a side cross-sectional view of the catheter of FIG. **1**, taken along line K-K.

FIG. **6** is an end cross-sectional view of the catheter of FIG. **1**, taken along line H-H.

FIG. **7** is a detailed perspective view of the distal end portion of the catheter of FIG. **1**, as delineated by line A-A.

FIG. **8** is a side cross-sectional view of a section of the distal end portion of FIG. **7**, as delineated by line E-E.

FIG. **9**A is an end view of a first embodiment of a distal assembly, with an off-edge, on axis configuration.

FIG. **9**B is an end view of a second embodiment of a distal assembly, with an off-edge, on axis configuration.

FIG. **9**C is an end view of a third embodiment of a distal assembly, with an off-edge, off axis configuration.

FIG. **10**A is a side view of an embodiment of an off-axis distal assembly approaching an ostium from one angle.

FIG. **10**B is a side view of another embodiment of an off-axis distal assembly approaching an ostium from an opposite angle.

FIG. **11** is an end cross-sectional view of a section of the distal end portion of FIG. **7**, taken along line C-C.

FIG. **12** is a side cross-section view of a distal tip of the distal end portion of FIG. **7**, taken along line D-D.

FIG. **13** is a perspective view of an embodiment of an irrigated ablation electrode.

FIG. **14** is a side cross-sectional view of a portion of an embodiment of a distal assembly carrying an irrigated ablation electrode.

FIG. **15** is a detailed view of another embodiment of a distal assembly carrying electrodes.

FIG. **16** is a side cross-sectional view of the control handle of FIG. **1**, taken along line L-L.

FIG. **17** is a partial detailed view of the control handle of FIG. **16**.

FIG. **18** is a top plan view of an alternate embodiment of a catheter in accordance with the present invention.

FIG. **19** is a detailed perspective view of the distal end portion of the catheter of FIG. **18**, as delineated by line B-B.

FIG. **20**A is a side perspective view of a first embodiment of a hollow shape-memory support member.

FIG. **20**B is a side perspective view of a second embodiment of a hollow shape-memory support member.

FIG. **20**C is a side perspective view of a third embodiment of a hollow shape-memory support member.

FIG. **21** is a schematic pictorial illustration of a system for ablation of tissue in the heart, in accordance with an embodiment of the present invention.

FIG. **22** is a schematic sectional view of a heart showing insertion of a catheter into the left atrium, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Lasso catheters, as described above, may be used for mapping and ablating tissue along an arc or curve surrounding an anatomical structure, such as the ostium of a pulmonary vein. The lasso is generally made thin and flexible, for purposes of maneuverability, with large ring electrodes to minimize electrical resistance. U.S. Patent Publication No. 2010/0168548, filed Dec. 30, 2008, which is assigned to the assignee of the present patent application and whose disclosure is incorporated herein by reference, describes an alternative design in which the lasso is thicker and stiffer. Even so, operators can find lasso catheters to be difficult to maneuver within the heart and position in such a way that the entire circumference of the lasso is in contact with the tissue, as is desirable for effective pulmonary vein isolation.

Embodiments of the present invention that are described hereinbelow provide probes, such as catheters, with improved lasso-type structures to facilitate maneuvering and positioning in the heart. Such catheters can be used to produce curved, circular, looped or otherwise closed ablation paths, as well as sensing electrical activity along a curve, circle, loop or closed pattern for electrical potential and anatomical mapping.

Referring to FIGS. **1** and **2**, a catheter **10** according to the disclosed embodiments comprises an elongated body that may include an insertion shaft or catheter body **12** having a longitudinal axis, and an intermediate section **14** distal of the catheter body that can be uni- or bi-directionally deflected off axis from the catheter body longitudinal axis. A resilient three-dimensional distal assembly **17**, with ring electrodes **19** disposed along a nonlinear or curved distal portion, extends from a generally straight transitional section **20** distal of the elongated body or the intermediate section **14**.

In accordance with a feature of the present invention, the curved distal portion defines, when unconstrained, a generally helical form **22**. The helical form is oriented obliquely relative to a longitudinal axis **25** of the intermediate section **14**. The term "obliquely", in the context of the present invention means that the plane in space that best fits the helical form is angled relative to the longitudinal axis **25** of the intermediate section **14**. The angle between the plane and the axis ranges between about 45 to 105 degrees, preferably between about 75 to 105 degrees, and more preferably about 90 degrees. Moreover, the helical form spirals or subtends in a predetermined manner. In one embodiment, the helical form subtends about 360 degrees. In another embodiment, the helical form subtends greater than 360 degrees, e.g., about 380 degrees.

Advantageously, the catheter **10** is designed to allow the helical form **22** to be contracted, thus decreasing its radius and/or pitch, by an operator manipulating a control handle **16** at the proximal end of the catheter body **12**, as explained below in further detail. Furthermore, as illustrated in FIG. **3**, the present catheter allows the overall configuration of the helical form **22** to be varied and adjusted, including significant expansion, whereby the helical form can be generally straightened, by means of a mandrel member **84** that is inserted alongside with or through a shape-memory member **50** that provides the helical form **22** of the distal assembly **17**, as also explained below in further detail.

The catheter enters a patient's body through a guiding sheath that has been inserted in a body cavity, such as a heart chamber. Due to the flexible construction of the distal assembly **17**, the helical form **22** readily straightens for insertion into the guiding sheath. The distal assembly is advanced axially in the guiding sheath until it moves past the distal end of the guiding sheath toward a tissue in the body, such as the inner heart wall. (The term "axial" refers to the direction parallel to the longitudinal axis of the catheter). When exposed and unconstrained, the distal assembly **17** reassumes the helical form **22** which is maneuvered to engage the tissue surface frontally with some or all of the electrodes **19** on the helical form contacting the tissue surface simultaneously, as shown in FIGS. **4**A and **4**B.

As discussed in detail further below, if the ostium is smaller in diameter than the helical form in its natural relaxed state, the operator can contract the helical form by means of a contraction wire manipulated via the control handle. If the ostium if larger in diameter than the helical form, the operator can expand or even significantly straighten the helical form by advancing a mandrel into the helical form that is straighter and stiffer than the shape-memory member of the helical form. In that regard, it is further understood that by providing a mandrel that is stiffer than the shape-memory member of the helical form, the form can generally assume the configuration or shape of the mandrel over the configuration of the shape-memory member.

According to an embodiment of the present invention, the catheter **10** has a three-dimensional mapping and/or ablation assembly **17** at its distal end. As shown in FIG. **1**, the catheter comprises an elongated catheter body **12** having proximal and distal ends, a deflectable intermediate section **14**, a control handle **16** at the proximal end of the catheter body, and a distal lasso-type assembly **17** mounted at the distal end of the deflectable intermediate section.

In the depicted embodiment of FIGS. **5**A and **5**B, the catheter body **12** comprises an elongated tubular construction having a single, axial or central lumen **18**. The catheter body **12** is flexible, i.e., bendable, but substantially non-

compressible along its length. The catheter body **12** can be of any suitable construction and made of any suitable material. A presently preferred construction comprises an outer wall **30** made of polyurethane or PEBAX. The outer wall **30** comprises an imbedded braided mesh of stainless steel or the like, as is generally known in the art, to increase torsional stiffness of the catheter body **12** so that, when the control handle **16** is rotated, the intermediate section **14** and distal assembly **17** will rotate in a corresponding manner.

The outer diameter of the catheter body **12** is not critical, but is preferably no more than about 8 french, more preferably 7 french. Likewise the thickness of the outer wall **30** is not critical, but is thin enough so that the central lumen **18** can accommodate any desired wires, cables and/or tubes. The inner surface of the outer wall **30** is lined with a stiffening tube **31** to provide improved torsional stability. The outer diameter of the stiffening tube **31** is about the same as or slightly smaller than the inner diameter of the outer wall **30**. The stiffening tube **31** can be made of any suitable material, such as polyimide, which provides very good stiffness and does not soften at body temperature.

The deflectable intermediate section **14** comprises a short section of tubing **15** having multiple lumens, each occupied by the various components extending through the intermediate section. In the illustrated embodiment of FIG. **6**, there are six lumens. Lead wire/thermocouple pairs **40**,**41** for each ring electrode pass through a first lumen **33**. A nonconductive protective sheath **42** may be provided. Irrigation tubing **43** for delivering irrigation fluid to the distal assembly **17** passes through a second lumen **34**. A contraction wire **44** passes through a third lumen **32**. A cable **46** for a position sensor assembly **48**, including a plurality of single axis sensors (SAS) positioned on the distal assembly **17**, passes through a fourth lumen **36**. For the distal assembly **17**, a shape-memory support member **50** surrounded by a nonconductive tubing **52**, e.g., a polyimide tubing, extends proximally from the distal assembly **17** for a relatively short distance into a fifth lumen **37**. A puller wire **54** for deflecting the intermediate section **14** passes through a sixth lumen **38**.

The multi-lumened tubing **15** of the intermediate section **14** is made of a suitable non-toxic material that is preferably more flexible than the catheter body **12**. A suitable material is braided polyurethane or PEBAX, i.e., polyurethane or PEBAX with an embedded mesh of braided stainless steel or the like. The plurality and size of each lumen are not critical, provided there is sufficient room to house the components extending therethrough. Position of each lumen is also not critical, except the position of the third lumen **32** for the distal assembly contraction wire **44** is preferably more aligned with an inner circumference of the helical form **22** of the distal assembly **17** so that proximal movement of the wire can readily contract the helical form. Moreover, the sixth lumen **38** for the deflection wire **54** is off-axis so that distal movement of the deflection wire accomplishes deflection toward the side on which lumen is off axis. Preferably, the third and sixth lumens **32** and **38** are diametrically opposed to each other.

The useful length of the catheter, i.e., that portion that can be inserted into the body excluding the distal assembly **17**, can vary as desired. Preferably the useful length ranges from about 110 cm to about 120 cm. The length of the intermediate section **14** is a relatively small portion of the useful length, and preferably ranges from about 3.5 cm to about 10 cm, more preferably from about 5 cm to about 6.5 cm.

A preferred means for attaching the catheter body **12** to the intermediate section **14** is illustrated in FIG. **5**. The proximal end of the intermediate section **14** comprises an inner circumferential notch that receives the outer surface of the stiffening tube **31** of the catheter body **12**. The intermediate section **14** and catheter body **12** are attached by glue or the like, for example, polyurethane. If desired, a spacer (not shown) can be provided within the catheter body **12** between the distal end of the stiffening tube **31** and the proximal end of the intermediate section **14** to provide a transition in flexibility at the junction of the catheter body **12** and the intermediate section, which allows the junction to bend smoothly without folding or kinking. An example of such a spacer is described in more detail in U.S. Pat. No. 5,964,757, the disclosure of which is incorporated herein by reference.

Distal the intermediate section **14** is the distal assembly **17**. Extending between the intermediate section **14** and the distal assembly **17** is a transitional section **20**, as shown in FIGS. **5** and **8**, having a tubing of suitable material, e.g., PEEK, with a central lumen that allows the various components extending therethrough to reorient before entering the distal assembly **17**.

As shown in FIG. **7**, at a base of the helical form **22**, the distal assembly **17** includes a generally straight proximal section **24** and a generally straight transverse section **21**. The distal end of the proximal portion **24** and the proximal end of the transverse portion form an "elbow" E at their junction such that the transverse portion **21** is generally transverse to the longitudinal axis **25** of the catheter **10** or at least the intermediate section **14**. In accordance with a feature of the present invention, the helical form **22** is mounted on the catheter in an "off-edge" configuration, where longitudinal axis **25** of the intermediate section **14** does not intersect the circumference of the helical form **22** but rather extends through the interior of the helical form as shown in FIGS. **9**A-**9**C.

In the embodiments of FIGS. **9**A and **9**B, center longitudinal axis **27** of the helical form **22** is generally aligned with the longitudinal axis **25** of the intermediate section, that is, the helical form **22** is axially centered ("on axis") on the longitudinal axis **25** of the intermediate section **14**. In the embodiment of FIG. **9**C, the respective longitudinal axes **25**, **27** are parallel and offset or off alignment relative to each other such that the helical form **22** is "off axis" relative to the longitudinal axis **25**. Where the interior of the helical form is defined by a centered X/Y Cartesian coordinate system, the elbow E generally assumes the central (0,0) position in an on-axis configuration, and an ($x \neq 0$, $y \neq 0$) position in an off-axis configuration. The transverse section **21** can have any length between about zero and the diameter of the helical form and can lie on any diametrical chord DC (FIGS. **9**A and **9**B) or nondiametrical chord NC (FIG. **9**C).

With reference to FIG. **7**, the helical form **22** can be defined by a radius r (or diameter d) and a pitch P (number of turns per unit length along its longitudinal axis). The diameter suitable for mapping or ablating a PV ostium can range between about 20 mm and 35 mm. The pitch can range between about 0.5" and 0.3".

In accordance with a feature of the present invention, the helical form **22** is tapered along its length. In one embodiment, the helical form spirals outwardly with an increasing radius from its proximal end to its distal end (FIG. **9**B). In another embodiment, the helical form spirals inwardly with a decreasing radius from its proximal end to its distal end (FIG. **9**A). In yet another embodiment, the helical form has a generally constant radius along its length (FIG. **9**C).

Depending on the arrangement of the transverse section **21**, including variations on the (x,y) position of the elbow E, different contact properties may be achieved with the distal assembly **17**. For example, a distal assembly with an on-axis

helical form **22** may be better suited for a head-on approach to an ostium OS (FIG. **4**B) where angle α between the longitudinal axes of the ostium and the catheter ranges between 0 and 15 degrees. An off-axis helical form **22** may be better suited for an off-angle approach to an ostium OS (FIGS. **10**A and **10**B) where angle α is greater than about 15 degrees. As shown in FIGS. **10**A and **10**B, an off-axis helical form **22** may provide better tissue/electrode contact when a head-on approach to a target ostium is not possible. When an axial force F is applied to the catheter, the distal assembly may be able to better distribute the force for greater surface contact between the electrodes and the ostium. In FIG. **10**A, the length of the transverse section **21** is greater than the radius of the helical form. In FIG. **10**B the length of the transverse section **21** is lesser than the radius of the helical form.

In the illustrated embodiment of FIG. **7**, the helical form **22** extends distally from the transverse section **21** and generally spirals about a longitudinal axis of the proximal section **24**. The helical form **22** has an outer diameter d preferably ranging to about 33 mm to about 35 mm. The helical form **22** can curve in a clockwise direction or a counterclockwise direction. The proximal section **24** of the distal assembly **17** has an exposed length of about 5 mm. The transverse section **21** has an exposed length of about 28 mm. The helical form has an exposed length of about 76 mm.

As shown in FIG. **11**, the distal assembly **17** is formed of multi-lumened tubing **56** which can be preformed with a desirable shape, including the helical form, as understood by one of ordinary skill in the art. In the disclosed embodiment, the tubing **56** has four off-axis lumens, namely, a first lumen **57** for the cable **46** and the SAS **48**, a second lumen **58** for the ring electrode wire pairs **40**, **41**, a third lumen **59** for irrigation fluid, and a fourth lumen **60** for the support member **50** and the contraction wire **44**. Again, position and sizing of the lumens is not critical, except the position of the fourth lumen **60** for the contraction wire **44** is preferably on an inner circumference of the helical form so that proximal movement of the wire can readily contract the helical form. The tubing **56** can be made of any suitable material, and is preferably made of a biocompatible plastic such as polyurethane or PEBAX.

In the depicted embodiment, the pre-formed support or spine member **50** of the distal assembly **17** extends through the fourth lumen **60** of the tubing **56** to define the shape of the helical form **22**. The support member **50** is made of a material having shape-memory, i.e., that can be straightened or bent out of its original shape upon exertion of a force and is capable of substantially returning to its original shape upon removal of the force. A particularly preferred material for the support member **50** is a nickel/titanium alloy. Such alloys typically comprise about 55% nickel and 45% titanium, but may comprise from about 54% to about 57% nickel with the balance being titanium. A preferred nickel/titanium alloy is Nitinol, which has excellent shape memory, together with ductility, strength, corrosion resistance, electrical resistivity and temperature stability.

The support member **50** has a cross-section of a predetermined shape that may be generally circular or generally rectangular, including a square shape. It is understood that a generally rectangular cross section can provide greater stiffness compared to a circular cross-section of a comparable size. Moreover, the support member can have a varying thickness along its length, for example, being thinner distally and thicker proximally so that a distal portion can be more readily contracted and a proximal portion can better withstand the load from an axial force that is applied when the distal assembly **17** comes into contact with target tissue.

In one embodiment, the support member **50** has a proximal end just proximal of the junction between the intermediate section **14** and the transitional section **21**, for example, about 2-3 mm proximal of the junction in the fifth lumen **37**. Alternatively, the support member **50** can extend further proximally into the intermediate section **14** via the fifth lumen or another lumen, the catheter body **12** via the central lumen **18**, or further into the control handle **16**, as desired or appropriate. In either instance, a nonconductive protective tubing **62** (e.g., a braided polyimide tubing) is provided in surrounding relationship with the support member **50** along its length.

The contraction wire **44** is provided to contract the helical form **22** to reduce its diameter. The contraction wire **44** has a proximal end anchored in the control handle **16**, which is used to manipulate the contraction wire. The contraction wire **44** extends through the central lumen **18** of the catheter body **12**, through the third lumen **32** of the intermediate section **14**, the central lumen of the transitional section **20** and the fourth lumen **60** of the distal assembly **17** to its distal end. In the fourth lumen **60** of the distal assembly **17**, the contraction wire **44** extends through the nonconductive protective tubing **62** along with the support member **50**. As mentioned, the fourth lumen **60** of the distal assembly **17** is positioned on the side of the helical form **22** closer to its center. With this arrangement, contraction of the helical form **22** is dramatically improved over arrangements where the position of the contraction wire **44** is not so controlled.

In one embodiment, the nonconductive protective tubing **62** comprises three layers, including an inner layer of polyimide over which a braided layer is formed, the braided layer comprising a braided stainless steel mesh or the like, as is generally known in the art. The braided layer enhances the strength of the tubing, reducing the tendency for the contraction wire **44** to straighten the preformed curve of the distal assembly **17**. A thin plastic layer of polytetrafluoroethylene is provided over the braided layer to protect the braided layer. The plastic tube **62** has a proximal end anchored to the distal end of the intermediate section **14**.

The support member **50** extends through the protective tubing **62** along with the contraction wire **44**. In the illustrated embodiment of FIG. **12**, the distal ends of the support member **50** and the contraction wire **44** (anchored in a crimped ferrule **51**) are soldered at **61** or otherwise attached to a small stainless steel tube **63**. With this arrangement, the relative positions of the contraction wire **44** and the support member **50** can be controlled so that the contraction wire **44** can be positioned on the inner side of the helical form **22** closer to the center of the helical form, as described above. The contraction wire **44** on the inside of the curve pulls the support member **50** to the inside of the curve, enhancing contraction of the helical form. Further, when the protective tubing **62** includes a braided layer, it minimizes the risk of the contraction wire **44** tearing through the multi-lumen tubing **56** of the distal assembly **17**. In the depicted embodiment, the distal end of the multi-lumen tubing **56** of the distal assembly **17** is sealed closed with a dome **64** of polyurethane glue or the like.

With reference to FIG. **5**, the compression coil **45** surrounding the contraction wire **44** extends from the proximal end of the catheter body **12** and through the third lumen **32** of the intermediate section **14**. The compression coil has a distal end at or near a mid-location in the transitional section **20**. The compression coil **45** is made of any suitable metal, preferably stainless steel, and is tightly wound on itself to

provide flexibility, i.e., bending, but to resist compression. The inner diameter of the compression coil is preferably slightly larger than the diameter of the contraction wire **44**. The outer surface of the compression coil is covered by a flexible, non-conductive sheath **47**, e.g., made of polyimide tubing. The compression coil preferably is formed of a wire having a square or rectangular cross-sectional area, which makes it less compressible than a compression coil formed from a wire having a circular cross-sectional area. As a result, the compression coil **45** keeps the catheter body **12**, and particularly the intermediate section **14**, from deflecting when the contraction wire **44** is manipulated to contract the distal assembly **17** as it absorbs more of the compression.

A series of ring electrodes **19** are mounted on predetermined locations on the helical form **22**, as shown in FIG. **7**. The electrodes can be made of any suitable solid conductive material, such as platinum or gold, preferably a combination of platinum and iridium or gold and platinum, and mounted onto the tubing with glue or the like. A suitable embodiment of an electrode adapted for ablation and irrigation is illustrated in FIGS. **13** and **14**. The ablation reservoir ("AR") electrode is generally cylindrical with a length greater than its diameter. In one embodiment, the length is about 3.0 mm, the outer diameter is about 2.8 mm, and the inner diameter is about 2.33 mm.

In the illustrated embodiment, the AR electrode has a side cross-section that can resemble a barrel with a side wall **65** (with a width, in one embodiment, of about 2.5 mm) that bulges radially such that a mid portion diameter MD is greater than end diameter ED at opposing end portions **66**. Curved transitional regions **67** are provided between the side wall **65** and the end portions **66** to provide an atraumatic profile without corners or sharp edges.

Notably, the mid portion diameter is greater than the outer diameter of the underlying tubing **56** of the distal assembly so that a reservoir or annular gap G exists around the exterior of the tubing **56**. The gap G provides improved fluid distribution from the third lumen **59** to the exterior of the AR electrode via an opening **68** provided in the outer wall of the tubing **56** and apertures **69** strategically formed and positioned in the side wall **65** of the AR electrode. The size of the opening **68** in the tubing **56** varies with the position along the length of the helical form **22**.

For optimum flow, the more distal an opening is along the helical form, the greater the size or cross-section of the opening and/or the plurality of openings for each AR electrode.

The apertures **69** are arranged the side wall **65** of an AR electrode in a predetermined pattern including axially offset rows. These apertures face outwardly promoting flow in a radial direction. Apertures are also provided in or near the curved transitional regions **67** to promote flow in an axial direction. Moreover, these apertures are particularly effective in minimizing charring and coagulation at or near the curved transitional regions which are likely to be "hot spots" resulting from higher current densities due to transitions in the electrode profile. In that regard, the plurality and/or cross-section of the apertures is greater at or near the curved transitional regions than in the side wall of the electrode so as to provide more cooling in the curved transitional regions. As such, the catheter can deliver more irrigation and consequently more cooling without increasing overall flow rate and overall fluid load on the patient.

In one embodiment, there are about 10 apertures on each end portion **66** and about 20 apertures on the side wall **65**. The pattern may be adjusted to further improve the flow distribution from each AR electrode. The pattern can be adjusted by adding or removing apertures, modifying the spacing between the apertures, modifying the location of the apertures on the ring electrodes and/or modifying the aperture geometry. Other suitable ring electrodes are described in US Patent Application Publication No. US2010/0168548 A1, the entire content of which is hereby incorporated by reference.

Irrigation fluid is delivered to the distal assembly by the irrigation tubing **43** whose proximal end is attached to a luer hub **100** proximal of the control handle **16** and receives fluid delivered by a pump (not shown). The irrigation tubing extends through the control handle **16**, the central lumen **18** of the catheter body **12**, the second lumen **34** of the intermediate section **14**, the central lumen of the transitional section **20** and a short distance distally into the third lumen **59** of the distal assembly **17**, for example, about 5 mm. The fluid enters the third lumen **59** where it exits the lumen via the openings **68** into the reservoir R of the AR electrodes where it exits the reservoir via the apertures **69** to outside of the AR electrodes to minimize charring.

The number of AR electrodes on the distal assembly **17** can vary as desired. Preferably the number of AR electrodes ranges from about six to about twenty, more preferably from about eight to about twelve. In one embodiment, the distal assembly **17** carries ten AR electrodes. The electrodes can be approximately evenly spaced around the helical form **22**, as shown in FIG. **7**.

The proximal end of each wire **50** is electrically connected to a suitable connector (not shown) distal of the control handle **16** for transmitting and/or receiving electrical signals to accomplish ablation. Each AR electrode is connected to a respective pair of wires **40**, **41**. In the disclosed embodiment, wire **40** of the wire pair is a copper wire, e.g. a number "40" copper wire.

The other wire **41** of the wire pair is a constantan wire. The wires of each pair are electrically isolated from each other except at their distal ends where they are twisted together, fed through a hole formed in the second lumen **58** of the distal assembly **17**, and soldered to their respective AR electrode (FIG. **14**). The wire pairs for each electrode extend from the control handle **16**, through the central lumen **18** of the catheter body **12**, the first lumen **33** of the intermediate section **14**, the central lumen of the transitional section **20**, and the second lumen **58** of the distal assembly **17**. Ablation energy, e.g., RF energy, is delivered to the AR electrodes via the wire **40** of the wire pairs. However, the wire pairs inclusive of their respective constantan wire can also function as temperature sensors or thermocouples sensing temperature of each AR electrode.

All of the wire pairs pass through one nonconductive protective sheath **42** (FIG. **6**), which can be made of any suitable material, e.g., polyimide, in surrounding relationship therewith. The sheath **42** extends from the control handle **16**, the catheter body **12**, the intermediate section **14**, the transitional section **20** and into the second lumen **58** of the distal assembly **17**, terminating just distal of the junction between the transitional section **20** and the distal assembly **17**, for example, about 5 mm into the second lumen **58**. The distal end is anchored in the second lumen by glue, for example, polyurethane glue or the like.

An alternate electrode arrangement is depicted in FIG. **15**. In this alternate embodiment, the distal assembly **17** has five AR electrodes and includes additional ring electrodes that are narrower than the AR electrodes. Such additional ring electrodes may be impedance recording (IR) electrodes that are electrically isolated from each other and the AR electrodes, and are adapted for recording impedance. In one

embodiment of the IR electrodes, the length is about 0.75 mm and the inner diameter is about 2.3 mm. The degree of success of mapping and/or ablation depends on tissue contact. Thus, tissue contact information is particularly useful with multi-electrode ablation catheters. Utilizing at least two independent pairs of IR electrodes (a "pair" hereinafter being any two electrodes, or preferably two most adjacent electrodes) with various size and spacing allows assessment of tissue contact by comparing impedance values and ratio at different frequencies/domains utilizing a single multi-electrode catheter.

The impedance can be further assessed at various frequencies/domains. For example, the ratio of impedance between a pair of IR electrodes and a pair of AR electrodes is used to assess tissue contact in terms of verifying contact and degree or amount of contact. With such isolated bi-polar IR electrodes, the catheter is adapted to perform simultaneous ablation, mapping (electrogram recording) and assessment of tissue contact.

The IR electrodes can be located in between each pair of AR electrodes or selected pairs of AR electrodes depending on the geometry of the distal assembly **17**, to provide accurate tissue contact verification via a comparison of the impedance between a pair of isolated (smaller) IR electrodes and the impedance between a pair of (larger) AR electrodes. In the illustrated embodiment of FIG. **15**, there are two IR electrodes between each adjacent pair of AR electrodes, for a total of 2(N−1) plurality of IR electrodes for N plurality of AR electrodes.

In another alternate embodiment as also illustrated in FIG. **7**, the distal assembly **17** includes electrically isolated bi-polar recording ring ("RR") electrodes located in between the AR electrodes to provide improved visualization of pulmonary vein ("PV") potentials. The catheter with such isolated bio-polar RR electrodes permits simultaneous ablation and electrogram recording without the need to reposition the catheter. To minimize far-field effects or any decrease in visualization resolution for more precise electrogram recording of PV potentials, the narrower bi-polar RR electrodes are positioned with a predetermined spacing in between each pair of AR electrodes or in between selected pairs of AR electrodes depending upon the geometry of the distal assembly.

As understood by one of ordinary skill in the art, two closely-spaced RR electrodes allow for more accurate detection of near field PV potential versus far field atrial signals, which is very important when trying to treat atrial fibrillation. Specifically, the near field PV potentials are very small signals whereas the atria, located very close to the pulmonary vein, provides much larger signals. Accordingly, even when the distal assembly **17** is placed in the pulmonary vein, it can be difficult for the physician to determine whether the signal is a small, close potential (from the pulmonary vein) or a larger, farther potential (from the atria). Closely-spaced bipoles permit the physician to more accurately determine whether he is looking at a close signal or a far signal. Accordingly, by having closely-spaced electrodes, one is able to better target the locations of myocardial tissue that have PV potentials and therefore allows the clinician to deliver therapy to the specific tissue. Moreover, the closely-spaced electrodes allow the physician to determine the exact anatomical location of the ostium by the electrical signal.

In one embodiment, a pair of AR electrodes are provided between each adjacent pairs of AR electrodes. Thus, for an M plurality of AR electrodes, there are 2(M−1) plurality of RR electrodes. In the illustrated embodiment, the distal assembly **17** carries 10 AR electrodes with a spacing of approximately 4.0 mm between adjacent AR electrodes. Where the distal assembly **17** also carries IR or RR electrodes, they can have a spacing of 1.0 mm between each other. Additionally, the distal most AR electrode can be a different size from the other AR electrodes so as to provide a visually distinguishing signal to the user when the catheter is being viewed under fluoroscopy. Specifically, because the distal assembly **17** is generally circular, it can be difficult for the user to determine the orientation of the helical form **22** and which electrodes are placed at a particular location in the heart. By having one AR electrode, such as the most distal AR electrode, being longer, the user has a reference point when viewing the catheter under fluoroscopy.

For any additional IR or RR electrodes as described above, additional lead wire pairs **40**, **41** are provided as appropriate. They extend through the second lumen **58** of the distal assembly **17**, the central lumen of the transitional section **20**, the first lumen **33** of the intermediate section **14**, the central lumen **18** of the catheter body **12** and into the control handle **16**.

The deflection puller wire **54** is provided for deflection of the intermediate shaft **14**. The deflection wire **54** extends through the central lumen **18** of the catheter body **12** and the sixth lumen **38** of the intermediate section **14**. It is anchored at its proximal end in the control handle **16**, and at its distal end to a location at or near the distal end of the intermediate section **14** by means of a T-bar **55** (FIGS. **6** and **8**) that is affixed to the sidewall of the tubing **15** by suitable material **49**, e.g., polyurethane. The distal end is anchored to the sidewall of the tubing **15** of the intermediate section as is generally described in U.S. Pat. No. 6,371,955, the entire disclosure of which is incorporated herein by reference. The puller wire **54** is made of any suitable metal, such as stainless steel or Nitinol, and is preferably coated with Teflon® or the like. The coating imparts lubricity to the puller wire. The puller wire preferably has a diameter ranging from about 0.006 to about 0.010 inch.

A second compression coil **53** is situated within the central lumen **18** of the catheter body **12** in surrounding relation to the puller wire **54** (FIG. **5**). The second compression coil **53** extends from the proximal end of the catheter body **12** to at or near the proximal end of the intermediate section **14**. The second compression coil **53** is made of any suitable metal, preferably stainless steel, and is tightly wound on itself to provide flexibility, i.e., bending, but to resist compression. The inner diameter of the second compression coil **53** is preferably slightly larger than the diameter of the puller wire **54**. The Teflon® coating on the puller wire allows it to slide freely within the second compression coil. Within the catheter body **12**, the outer surface of the second compression coil **53** is covered by a flexible, non-conductive sheath **47**, e.g., made of polyimide tubing. The second compression coil **53** is anchored at its proximal end to the outer wall **30** of the catheter body **12** by a proximal glue joint and to the intermediate section **14** by a distal glue joint.

Within the sixth lumen **38** of the intermediate section **14**, the puller wire **54** extends through a plastic, preferably Teflon®, puller wire sheath, which prevents the puller wire **54** from cutting into the wall of the tubing **15** of the intermediate section **14** when the intermediate section **14** is deflected.

Longitudinal movement of the contraction wire **44** relative to the catheter body **12**, which results in contraction of the helical form of the distal assembly **17**, is accomplished by suitable manipulation of the control handle **16**. Similarly, longitudinal movement of the deflection wire **54** relative to

the catheter body **12**, which results in deflection of the intermediate section **14**, is accomplished by suitable manipulation of the control handle **16**. Suitable control handles for manipulating more than one wire are described, for example, in U.S. Pat. Nos. 6,468,260, 6,500,167, and 6,522,933, the disclosures of which are incorporated herein by reference. Suitable control handles for manipulating lasso-type catheters are described in U.S. Patent Publication No. 2011/0054287, filed Aug. 28, 2009, and U.S. Patent Publication No. 2011/0054446, filed Aug. 28, 2009, the entire disclosures of which are incorporated herein by reference.

In one embodiment, the catheter includes a control handle **16** as shown in FIGS. **16** and **17**. The control handle **16** includes a deflection control assembly that has a handle body **74** in which a core **76** is fixedly mounted and a piston **78** is slidably mounted over a distal region of the core **76**. The piston **78** has a distal portion that extends outside the handle body. A thumb knob **80** is mounted on the distal portion so that the user can more easily move the piston longitudinally relative to the core **76** and handle body **74**. The proximal end of the catheter body **12** is fixedly mounted to the distal end of the piston **78**. An axial passage **79** is provided at the distal end of the piston, so that various components, including lead wires **40**, **41**, contraction wire **44**, deflection wire **54**, sensor cable **46** and irrigation tubing **43** that extend through the catheter body **12** can pass into and if appropriate, through the control handle. For example, the lead wires **40**, **41** can extend out the proximal end of the control handle **16** or can be connected to a connector that is incorporated into the control handle, as is generally known in the art.

The proximal end of the deflection wire **54** enters the control handle **16**, and is wrapped around a pulley **82** and anchored to the core **76**. Longitudinal movement of the thumb knob **80** and piston **78** distally relative to the handle body **74** and core **76** draws the proximal end of the deflection wire **54** distally. As a result, the deflection wire **54** pulls on the side of the intermediate section **14** to which it is anchored, thereby deflecting the intermediate section in that direction. To straighten the intermediate section **14**, the thumb knob **80** is moved proximally which results in the piston **78** being moved proximally back to its original position relative to the handle body **74** and core **76**.

The control handle **16** is also used for longitudinal movement of the contraction wire **44** by means of a rotational control assembly. In the illustrated embodiment, the rotational control assembly includes a cam handle **71** and a cam receiver **72**. By rotating the cam handle in one direction, the cam receiver is drawn proximally to draw on the contraction wire **44**. By rotating the cam handle in the other direction, the cam receiver is advanced distally to release the contraction wire. For example, where the helical form **22** has an original outer diameter of about 35 mm, tightening of the helical form by means of the contraction wire can reduce the outer diameter to about 20 mm. The contraction wire **44** extends from the catheter body **12** into the control handle **16**, through the axial passage in the piston **78** and through the core **76** to be anchored in an adjuster **75** by which tension on the contraction wire can be adjusted.

In one embodiment, the position sensor **48** includes a plurality of single axis sensors ("SAS") carried on the cable **46** that extends through the first lumen **57** of the distal assembly **17** (FIG. **11**), where each SAS occupies a known or predetermined position on the helical form **22**.

The cable **46** extends proximally from the distal assembly **17** through the central lumen of the transitional section **20**, the fourth lumen **36** of the intermediate section **14** (FIG. **6**), the central lumen **18** of the catheter body **12**, and into the control handle **16**. Each SA sensor can be positioned with a known and equal spacing separating adjacent SA sensors. In the disclosed embodiment, the cable carries three SASs that are positioned under the distal-most AR electrode, the proximal-most AR electrode, and a mid AR electrode, for sensing location and/or position of the helical form. Where the distal assembly carries ten AR electrodes, the SASs are under electrodes AR**1**, AR**5** and AR**10** (FIG. **7**). The SASs enable the helical form to be viewed under mapping systems manufactured and sold by Biosense Webster, Inc., including the CARTO, CARTO XP and NOGA mapping systems. Suitable SASs are described in U.S. Patent Publication No. 2012/0172703, filed Dec. 30, 2010, the entire disclosure of which is incorporated herein by reference.

In an alternative embodiment of the present invention as illustrated in FIGS. **18** and **19**, the distal assembly **17** includes a curved portion that has a semi-circular form or a crescent shape **22'**. The semi-circular form **22'** has generally the same structure and construction as the helical form **22**, except the semi-circular form subtends an angle no greater than about 180 degrees. The circular form is particularly useful where the patient has a larger PV ostium or where two PV are in such close proximity to each other that they share a common ostium. In one embodiment, the outer diameter of the crescent form is about 38.0 to 40.0 mm, which can be reduced to about 20.0 mm when tightened by the contraction wire **44**. For example, where the crescent form carries seven AR electrodes, the SASs are located under AR**1**, AR**4** and AR**7** (FIG. **19**).

In another alternative embodiment of the present invention, as illustrated in FIG. **3**, the catheter has a distal assembly **17** whose form **22** (whether it is helical, semi-circular or otherwise) can be varied by means of a stiffener or mandrel **84** that is extended through the shape memory support member **50** of the distal assembly. As illustrated in FIGS. **20**A-**20**C, the shape memory support member **50** is tubular (but not necessarily with a circular cross-section) or otherwise hollow so as to be able to receive the mandrel whose shape and stiffness/flexibility differ from those of the support member **50**. In one embodiment as shown in FIG. **20**A, the hollow support member **50**A includes multiple shape memory wires **90** that are coiled together forming a helical hollow strand tubing. Alternatively, a hollow support member **50**B is formed from a tube with a spiral cut **92** (e.g., by laser) along the length of the member to provide greater flexibility. The cut is made at an angle β between about 30-80 degrees, and preferably about 65 degrees, from the axial direction. As shown in FIG. **20**B, the spiral cut can be made with a smooth and linear edge **94**. In one detailed embodiment, the outer diameter of the member **50**B is about 0.25 mm and the inner diameter is about 0.20 mm. The width of a strip WS between adjacent cuts is approx. 0.024 mm and the width of the cut WC is approx. 0.002 mm. Alternatively, as shown in FIG. **20**C, the spiral cut can have an interlocking pattern **96**, e.g., a dovetail pattern, so that the member can provide greater flexibility without elongation in the axial direction. In one detailed embodiment, the width of a strip WS between adjacent cuts is a bout 0.023 mm. The widest portion of each dovetail WD is about 0.005 mm and the depth of the dovetail DD is about 0.006 mm and the width of the cut WC is about 0.001 mm.

As illustrated in FIG. **3**, the generally circular form of the distal assembly (a helical form **22** in this instance) yields to assume the more expanded preformed shape of the mandrel **84** received therein and unwinds to a form with significantly

less curvature (shown in solid lines). Upon removal of the mandrel **84** from the distal assembly **17**, the helical form **22** reassumes the predetermined shape of the shape memory support member **50** (shown in broken lines).

It is understood that in these embodiments, the hollow support member **50** can extend proximally to at least a proximal portion of the catheter body **12** that remains outside of the patient, if not through control handle **16** so the proximal end is accessible to the operator for inserting the mandrel. The proximal end can exit the catheter body at a location near the control handle or it can extend through the control handle and exit the proximal end of the control handle to be accessed by the operator.

Thus, the operator can expand or even significantly straighten the form of the distal assembly by advancing the mandrel **84** through the hollow support member **50**A, **50**B, **50**C where the mandrel is straighter and stiffer than the hollow shape-memory member. In that regard, it is understood that by providing a mandrel that is stiffer than the shape-memory member of the form of the distal assembly, the form can generally assume the configuration or shape of the mandrel over the configuration of the shape-memory member.

The present catheter **10** is a steerable, multi-electrode, irrigated luminal catheter. The catheter is deployed in a target region of the body, e.g., the atria of the heart, through a guiding sheath. The catheter is designed to facilitate electrophysiological mapping of the target region, e.g., the atria, and to transmit energy, e.g., radiofrequency (RF) current, to the catheter electrodes for ablation purposes. For ablation, the catheter is used in conjunction with a multi-channel RF generator and irrigation pump.

The configuration of the catheter permits the catheter to sit at an opening of a tubular formation, e.g., the PV ostia, with consistent circumferential contact with the tissue. Intracardia signals are recorded by an EP Recording System and the location of the catheter is visualized by fluoroscopy. Once the catheter is in the desired location, energy is delivered (to multiple electrodes simultaneously or selectively) to the veins ostium in unipolar or bipolar mode resulting in PV isolation.

In one embodiment, ablation is delivered at a set wattage on the multi-channel RF generator. During ablation the multi-channel RF generator monitors the temperature of the ring electrode(s) involved and reduces the wattage if the temperature exceeds a value set by the user. The multi-channel RF generator routes the RF current through the selected ring electrodes and catheter temperature information is sent from the thermocouple on the catheter to the generator.

During ablation, an irrigation pump is used to deliver normal heparinized saline to the ring electrodes to cool the ring electrodes to prevent blood from coagulating. The apertures in the ring electrodes facilitate irrigation of the ablation areas of the catheter. Where deeper lesions are desired, the greater flow distribution (without greater flow rate) of each ring electrode via the apertures reduces the increased risk of charring and coagulum on the ablation surfaces that would normally be encountered when the amount of power delivered to the electrode/tissue interface is increased. A greater flow distribution from each ring electrode which leads to improved irrigation efficiency offers advantages, including (1) higher power delivery without increasing fluid pump flow rate, (2) ability to use currently available, flow rate-limited pumps, (3) eliminate need to use multiple pumps, and/or (4) reduction in fluid load on patient during ablation procedure.

FIG. **21** is a schematic pictorial illustration of a system S for ablation of tissue in a heart **126** of a patient **128**, in accordance with an embodiment of the present invention. An operator **122**, such as a cardiologist, inserts a catheter **124** through the vascular system of the patient so that the distal end of the catheter enters a chamber of the patient's heart. Operator advances the catheter so that the end section **222** of the catheter engages endocardial tissue at a desired location or locations, as shown in FIG. **21**. Catheter **124** is connected by a suitable connector at its proximal end to a console **130**. The console comprises an RF generator for applying RF energy through electrodes on the end section of the catheter in order to ablate the tissue contacted by the distal section. Alternatively or additionally, catheter may be used for other diagnostic and/or therapeutic functions, such as intracardiac electrical mapping or other types of ablation therapy.

In the pictured embodiment, system S uses magnetic positioning sensing to determine position coordinates of the distal assembly of the catheter inside heart. To determine the position coordinates, a driver circuit **134** in console **130** drives field generators **132** to generate magnetic fields within the body of patient. Typically, field generators comprise coils, which are placed below the patient's torso at known positions external to the body. These coils generate magnetic fields in a predetermined working volume that contains heart. One or more magnetic field sensors within the end section of catheter generate electrical signals in response to these magnetic fields. The console **130** processes these signals in order to determine the position (location and/or orientation) coordinates of the distal assembly **222** of the catheter, and possibly also the deformation of the distal assembly, as explained below. Console may use the coordinates in driving a display **138** to show the location and status of the catheter. This method of position sensing and processing is described in detail, for example, in PCT International Publication WO 96/05768, whose entire disclosure is incorporated herein by reference, and is implemented in the CARTO system produced by Biosense Webster Inc. (Diamond Bar, Calif.).

Alternatively or additionally, system may comprise an automated mechanism (not shown) for maneuvering and operating catheter within the body of patient. Such mechanisms are typically capable of controlling both the longitudinal motion (advance/retract) and the rotation of catheter. In such embodiments, console generates a control input for controlling the motion of the catheter based on the signals provided by the position sensing system.

Although FIG. **21** shows a particular system configuration, other system configurations may be used in alternative embodiments of the present invention. For example, the methods described hereinbelow may be applied using position transducers of other types, such as impedance-based or ultrasonic position sensors. The term "position transducer" as used herein refers to an element mounted on or in catheter that causes console to receive signals indicative of the coordinates of the element. The position transducer may thus comprise a receiver in the catheter, which generates a position signal to the control unit based on energy received by the transducer; or it may comprise a transmitter, emitting energy that is sensed by a receiver external to the probe. Furthermore, the methods described hereinbelow may similarly be applied in mapping and measurement applications using not only catheters, but also probes of other types, both in the heart and in other body organs and regions.

FIG. **22** is a schematic sectional view of heart **126**, showing insertion of catheter **124** into the heart, in accordance with an embodiment of the present invention. To

insert the catheter in the pictured embodiment, the operator first passes a sheath **140** percutaneously through the vascular system and into right atrium **144** of the heart through ascending vena cava **142**. The sheath penetrates through interatrial septum **148**, typically via the fossa ovalis, into left atrium **146**. Alternatively, other approach paths may be used. Catheter is then inserted through the sheath until an end section **222** of the catheter passes out of the distal opening of the end of the sheath **140** into the left atrium **146**.

Operator aligns the longitudinal axis of sheath **140** (and of catheter) inside left atrium **146** with the axis of one of pulmonary veins. He may use the thumb knob **80** of the control handle **16** to deflect the intermediate section **14** in directing the distal assembly **222** toward the target ostium. The operator may carry out this alignment using the position sensing methods described above, along with a pre-acquired map or image of heart. Alternatively or additionally, the alignment may be performed under fluoroscopic or other means of visualization. The operator advances the catheter toward the target pulmonary vein so that the distal assembly **222** contacts the ostium and either partly or fully surrounds the vein. By manipulating the cam handle **71**, the helical form of the distal assembly **222** is contracted to fit the PV ostium. In the disclosed embodiment, the contraction wire **44** is drawn proximally by the cam receiver **72** to tighten and decrease the diameter of the helical form when the cam handle is turned in one direction. By turning the cam handle in the opposition direction, the cam receiver releases the contraction wire to allow the helical form to expand and return to its original diameter.

The operator can then rotate the catheter about its axis within the sheath so that the distal assembly traces an annular path around the inner circumference of the vein. Meanwhile, the operator actuates RF generator to ablate the tissue in contact with the AR electrodes along the path. Simultaneously, impedance and/or PV potential recordings can be made with the IR and/or RR electrodes. After completing this procedure around one pulmonary vein, the operator may shift the sheath and catheter and repeat the procedure around one or more of the other pulmonary veins.

The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention. Any feature or structure disclosed in one embodiment may be incorporated in lieu of or in addition to other features of any other embodiments, as needed or appropriate. As understood by one of ordinary skill in the art, the drawings are not necessarily to scale. Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.

What is claimed is:

1. A catheter comprising:
an elongated body having a longitudinal axis;
a distal assembly distal the elongated body, the distal assembly having a hollow shape-memory support member defining a first curvature defining a helical form;
at least one irrigated ablation ring electrode mounted on the helical form;
a control handle proximal the elongated body;
a contraction wire extending through the elongated body and the distal assembly, wherein longitudinal movement of the contraction wire results in contraction of the helical form; and
a mandrel configured for insertion through the hollow shape-memory support member, the mandrel having a second curvature different from the first curvature of the helical form;
wherein the helical form has an on-axis configuration such that a central longitudinal axis of the helical form is axially aligned with the longitudinal axis of the elongated body.

2. A catheter of claim **1**, wherein the control handle includes a first control member configured to actuate the contraction wire to contract the helical form.

3. A catheter of claim **1**, further comprising a deflection wire extending through the elongated body, wherein the control handle includes a second control member configured to actuate the deflection wire to deflect a portion of the elongated body.

4. A catheter of claim **1**, wherein the irrigated ablation ring electrode has at least one aperture configured to pass fluid from inside the ring electrode to outside the ring electrode in a radial direction.

5. A catheter of claim **1**, wherein the irrigated ablation ring electrode has at least one aperture configured to pass fluid from inside the ring electrode to outside the ring electrode in an axial direction.

6. A catheter of claim **1**, further comprising at least one ring electrode adapted to measure impedance.

7. A catheter of claim **1**, further comprising at least one ring electrode adapted to measure PV potentials.

8. A catheter comprising:
an elongated body having a longitudinal axis;
a distal assembly distal the elongated body, the distal assembly having a hollow support member defining a first predetermined form having a first curvature;
at least one electrode mounted on the distal assembly;
a control handle proximal the elongated body;
a contraction wire extending through the elongated body and the distal assembly, wherein longitudinal movement of the contraction wire results in contraction of the first predetermined form; and
a mandrel defining a second predetermined form having a second curvature that is different from the first curvature of the first predetermined form, the mandrel being adapted for insertion into the hollow support member.

9. A catheter of claim **8**, wherein the first predetermined form of the distal assembly is generally helical.

10. A catheter of claim **8**, wherein the second predetermined form of the mandrel is generally crescent.

11. A catheter of claim **8**, wherein the first curvature of the first predetermined form of the distal assembly is greater than the second curvature of the second predetermined form of the mandrel, and the second curvature of the second predetermined form of the mandrel is lesser than the first curvature of the first predetermined form of the distal assembly.

12. A catheter of claim **8**, wherein the first predetermined form has an on-axis configuration such that a central longitudinal axis of the first predetermined form is axially aligned with the longitudinal axis of the elongated body.

13. A catheter of claim **8**, wherein the first predetermined form of the distal assembly has an off-edge configuration such that the predetermined form has a central longitudinal axis that is parallel without axial alignment with a longitudinal axis of the elongated body.

14. A catheter of claim 8, wherein the hollow support member includes a hollow strand tubing.

15. A catheter of claim 8, wherein the hollow support member includes a tubular member with a spiral cut along its length.

16. A catheter of claim 15, wherein the spiral cut includes an interlocking pattern.

17. A catheter comprising:

an elongated body having a longitudinal axis;

a distal assembly distal the elongated body, the distal assembly having a hollow shape-memory support member and a first curvature defining a generally circular form;

at least one irrigated ablation ring electrode mounted on the generally circular form;

a control handle proximal the elongated body;

a contraction wire extending through the elongated body and the distal assembly, wherein longitudinal movement of the contraction wire results in contraction of the generally circular form; and

a mandrel configured for insertion through the hollow shape-memory support member, the mandrel having a second curvature that is different from the first curvature of the generally circular form,

wherein the generally circular form has an off-edge configuration such that the circular form spirals about a longitudinal axis of the elongated body.

18. A catheter of claim 17, wherein the generally circular form has an off-axis configuration such that the central longitudinal axis of the circular form is axially offset from the longitudinal axis of the elongated body.

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